UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 20, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 4 A.M. SESSION

(Pages 655 - 779)

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I N D E X

EXAMINATION

EXHIBITS

10:01:31

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:33:38

THE COURT: Thank you. Please be seated.

Morning, everybody.

MR. LOPEZ: Good morning, Your Honor.

MR. NORTH: Good morning, Judge.

THE COURT: Sorry I'm late. I've been locked in our

08:33:55 ultrasecure parking garage downstairs for the last 15 minutes.

All right. As I think you've probably seen, over the weekend I got through the last five deposition transcripts and got an order out on those, so I think I've covered all of the depositions that you've given to me.

08:34:18

I also filed last night a ruling on the Simon Nitinol filter evidence.

What matters do you all wish to raise this morning?

Let's start with plaintiff's counsel.

MR. LOPEZ: Just on the Simon Nitinol filter issue,

08:34:37 Your Honor, there was one thing in your order that stated -- we did not get complaint files on the Simon Nitinol filter. I just wanted the Court to be aware of that. It might be important. We did not get their adverse event complaint files.

08:34:50

THE COURT: You did receive the adverse event

08:34:53 statistical information?

MR. LOPEZ: We got charts and stuff like that, but we didn't get the actual complaint files for us to look at.

THE COURT: Okay.

08:35:00 Do you have other matters you wish to raise this morning?

MR. NORTH: Your Honor, there is a deposition objection we have as far as an interpretation of something. If I may, my colleague, Ms. Kowalzyk, will address that, and

08:35:14 then I have one quick logistical issue after that to raise.

MS. KOWALZYK: Good morning, Your Honor.

THE COURT: Good morning.

MS. KOWALZYK: It's our understanding that after they finish playing the deposition of Ms. Hudnall, the plaintiffs

08:35:27 want to play a very short clip of the deposition of a doctor named Dr. Gary Cohen. And as far as with respect to showing an exhibit at the same time it's showing the testimony, they want to show an exhibit that was not designated in the transcript. And the portion of transcript that they want to

08:35:55 show this with is simply -- it's a memo. It's an e-mail internal at Bard, the exhibit, and it attaches a memo that was prepared at Dr. Cohen's hospital, and they want to show the internal e-mail discussion at Bard, including e-mails that Dr. Cohen was not privy to. And the only testimony that is

08:36:21 designated that goes with this exhibit is simply describing

08:36:24 the fact that the memo exists. And so --

THE COURT: So what is it that you are asking me to do on that issue?

MS. KOWALZYK: Well, we don't think that the exhibit 08:36:37 has been properly designated so that we could properly raise the objections we would raise in the transcript.

THE COURT: Say that again.

MS. KOWALZYK: In the transcript they didn't designate, highlight, the testimony or even the line where the 08:36:52 exhibit would be introduced or where it was numbered. That portion of the transcript is more than 20 pages away from the ten lines that they've got designated.

THE COURT: So what is it you want me to do on this issue?

08:37:09 MS. KOWALZYK: Your Honor, there's a lack of foundation. And so we don't think that they should be able to show the memo at the same time that they show -- that they play that portion of deposition.

THE COURT: Do you have an objection to their playing 08:37:22 that portion of the deposition?

MS. KOWALZYK: We raised an objection in the transcript just with respect to the words, but of course didn't know they were planning to put up an exhibit at the same time that isn't really related to the testimony that they 08:37:39 want to put it side-by-side with.

08:37:41 THE COURT: And did I rule on that objection?

MS. KOWALZYK: You did. We made a 401, 402, 403 objection.

THE COURT: And how did I rule?

08:37:51 MS. KOWALZYK: You overruled it.

THE COURT: So the testimony is going to be played, and you don't want them to be able to display the memo at the same time the testimony is being displayed?

MS. KOWALZYK: Correct.

08:38:02 THE COURT: Okay.

MS. MATARAZZO: Your Honor, this is the issue that came up with Dr. Ciavarella on day 2. The testimony is designated. It's designated at page 123. I can show it to you. It's very clear that they're talking about the memo. It

08:38:18 was marked -- it was marked 20 pages earlier. We didn't highlight that, but it is very clear they're talking about the memo.

They're talking about the fact Dr. Cohen sent the memo to Bard, which is what the evidence -- what the e-mails

08:38:31 show, and the memo is attached to the e-mail. And we would like to be able to show the memo when it's being discussed and get it into evidence through Dr. Cohen.

And this was the exact same issue that came up with Dr. Ciavarella on day 2. They didn't object on foundation

08:38:48 grounds. You overruled the objection, and you allowed the

08:38:52 exhibit to come in.

THE COURT: Is the exhibit one that has been admitted in evidence so far?

MS. MATARAZZO: It has not been admitted into
08:39:00 evidence yet, Your Honor. We would like to offer it through Dr. Cohen, the same way we did that exhibit with Dr. Ciavarella.

THE COURT: All right. Is there an evidentiary objection to the exhibit?

08:39:09 MS. KOWALZYK: Yes, Your Honor. There's no foundation.

THE COURT: Meaning no foundation -- explain what you mean.

MS. KOWALZYK: They don't lay the foundation with
08:39:17 this witness for this exhibit that they intend to show. And the testimony that they've designated only pertains to the existence of the memo. It certainly doesn't discuss the three pages of e-mails leading up to the memo that is sort of the lead-in and the portion of the exhibit that I believe they've
08:39:40 got highlighted.

THE COURT: Well, when you say there's no foundation, what's the evidentiary objection you're making? Is it hearsay? Are you saying that it hasn't been established as a business record? Are you saying it's not authenticated under
08:39:55 Rule 901?

08:39:58 MS. KOWALZYK: They haven't laid the proper foundation under 602.

THE COURT: So you're saying they haven't shown that this witness knows the contents of the document?

08:40:09 MS. KOWALZYK: That's right, Your Honor.

THE COURT: Okay.

MS. MATARAZZO: Your Honor, I have a copy of the testimony if you'd like to see it. It's very clear that he knows the contents. He wrote it. The question is "You would

08:40:19 agree with me that the memo that you sent to Bard was prepared by the folks at Temple doing investigation" --

THE COURT: Why don't you bring it up to me so I can look at it, if you would.

MS. MATARAZZO: Yeah. May I approach the clerk?

08:40:32 THE COURT: Um-hmm.

All right. So what I have in front of me is page 123 of the deposition. There's 11 lines designated.

Are these the lines you're speaking of?

MS. KOWALZYK: Yes, Your Honor, and --

08:40:56 THE COURT: Let me just read them.

This is Dr. Cohen, who is at Temple; right?

MS. MATARAZZO: Yes, Your Honor.

THE COURT: Do you agree that he sent this memo?

MS. KOWALZYK: The deposition in its entirety, I

08:41:36 don't believe shows that Dr. Cohen himself sent it.

08:41:40 THE COURT: Well, it says, "You would agree with me that the memo that you sent to Bard was prepared by folks at Temple doing investigations about migratory deaths of the Recovery?"

08:41:51 "Answer: By Temple risk management, yes."

MS. KOWALZYK: That's right. That's right, Your Honor.

THE COURT: So it sounds like he sent it to Bard.

MS. KOWALZYK: I agree.

08:42:03 MS. MATARAZZO: And, Your Honor, that is in the exhibit.

THE COURT: So it seems to me he would have knowledge of what's in the memo. He apparently sent it to Bard to communicate to Bard what was in the memo.

08:42:11 MS. KOWALZYK: The memo itself. But the three pages that precede that in the exhibit that they want to introduce and show are internal e-mail discussions about it at Bard, and he is not on those e-mails.

MS. MATARAZZO: Your Honor, may I --

08:42:24 THE COURT: Are those going to be displayed -- the e-mails being displayed during the deposition?

MS. KOWALZYK: The highlighted version that counsel showed me this morning did have those highlighted, yes.

THE COURT: So are you showing e-mails internal to

08:42:37 Bard as part of this deposition excerpt?

08:42:41 MS. MATARAZZO: Your Honor, I have to check with our videographer and how he cut it. I apologize, I can't answer that.

THE COURT: It seems to me that he can testify about 08:42:49 the memo he sent to Bard. But unless he's privy to the Bard internal e-mails, it seems to me those can't come in based on his testimony and ought not be displayed to the jury.

MS. MATARAZZO: Understood, Your Honor. So I will make sure that just the memo, anything that's shown will be 08:43:07 just the memo itself or the e-mail of Dr. Cohen forwarding the memo to Bard, if that's agreeable.

THE COURT: Does that satisfy the objection?

MS. KOWALZYK: Yes, Your Honor.

THE COURT: Okay. If you would do that, that would 08:43:18 be great.

MR. NORTH: I had a silly question about the Judge's courtroom protocol, if I could. In the past when I've tried cases, I've sometimes written on pads highlights of a witness's testimony. I understand the Court's rule about 08:43:31 staying at the podium.

Does the Court have any objection, obviously with the understanding the jury will be told that anything the lawyers say is not evidence, if I write down highlights while a witness is testifying?

08:43:42 THE COURT: Where would you be and how would --

08:43:44 MR. NORTH: I would be right here at the podium and do it right here under the Elmo, as opposed to using the pad.

THE COURT: And then what will you do with that?

MR. NORTH: I would like to use the notes, it would
08:43:54 be mostly on cross-examination of the plaintiffs' experts, in closing to just remind the jury what the expert said.

THE COURT: I don't have a problem with that. With either side doing that.

MR. NORTH: Okay. Thank you, Your Honor. That's
08:44:07 all.

MR. O'CONNOR: Along those lines, Your Honor, I think we have some experts coming in this morning who we have radiograph imaging studies to show the jury that they've enlarged, and while I would normally have them write on it,
08:44:22 I've had them just write annotations on the imaging studies beforehand so we can save time and move through just to show people, the jury, where he is looking at, and I just want to make sure there's not going to be an objection to that.

THE COURT: Have you shown that to the defendants?

08:44:39 MR. O'CONNOR: We've sent those to you.

MR. NORTH: I'll look at them. I'm sure there won't be objection.

MR. O'CONNOR: Because I'm going to ask to move them into evidence.

08:44:46 THE COURT: With the notations on them?

08:44:47 MR. O'CONNOR: Yeah. And I think the annotations are just pretty straightforward. They're not opinions, they're just showing where things are at.

THE COURT: Okay. Well, make sure defendants can see 08:44:54 them. If there's an objection, I'll be happy to rule on it at the time.

All right. Are there other matters that we need to take up today or before we get the jury in?

MR. NORTH: Nothing for the defense, Your Honor.

08:45:09 MS. REED ZAIC: I would, maybe just in the vernacular, give the Court a heads-up that tomorrow morning at 8:30, we would like to address the ruling in motion in limine with regard to the warning letter, the three paragraphs that Your Honor stated in your order that they may be relevant but 08:45:34 they need to be handled outside of the presence of the jury, just so you're on notice that we'll address that tomorrow morning.

THE COURT: Okay. Why don't you confer ahead of time --

08:45:44 MS. REED ZAIC: Sure.

THE COURT: -- just so that everybody knows the position, and that way we'll save some time when we address it.

MS. REED ZAIC: Absolutely.

08:45:49 Who are the experts that are going to be called

today?

MR. O'CONNOR: Derek Muehrcke, a cardiothoracic surgeon --

THE COURT: I can't hear you, Mr. O'Connor.

MR. O'CONNOR: Your Honor, Derek Muehrcke, MD, and then Darren Hurst, MD. Cardiothoracic and intravascular.

THE COURT: Muehrcke and?

MR. O'CONNOR: Hurst.

Muehrcke is M-U-E-H-R-C-K-E. Derek. And Hurst is H-U-R-S-T.

THE COURT: Okay.

All right. Go ahead about your business. We'll plan to get the jury in here at 9 o'clock.

MR. LOPEZ: Thank you, Your Honor.

THE COURT: By the way, are we just starting with the playing of the deposition of Ms. Hudnall again this morning?

MR. LOPEZ: We're going to finish that.

THE COURT: Okay.

MR. LOPEZ: There's a portion in it, you only have one original of these tapes, and it's a little distorted. It's not so distorted we have to stop it and read it, but if you or I could warn the jury that it's not a technical difficulty here, that's just the original. The voice is fine, but the -- all of a sudden the witness herself is going to look weird.

08:47:02 THE COURT: Okay. I'll try to remember to do that. If I forget, you can do that.

MR. LOPEZ: Okay.

(Recess was taken from 8:47 to 9:01. Proceedings resumed in open court with the jury present.)

08:50:58 THE COURT: Thank you. Please be seated.

Good morning, ladies and gentlemen.

JURORS: Good morning.

THE COURT: Thank you all for being with us again this morning. Hope you had a nice weekend.

09:01:59 We're going to pick up this morning where we left off on Friday, and that is watching the deposition of Ms. Hudnall.

Counsel have advised me that there's a point in this deposition where the picture gets fuzzy or a little unstable. The sound is still good. That's not an equipment problem, apparently that just was the way the videotape came. So try not to be distracted by that.

09:02:16 And plaintiffs, you may proceed.

(Videotaped deposition played.)

09:16:40 MR. LOPEZ: Thank you, Your Honor.

At this time I would like to move into evidence the exhibits that have been identified prior to the deposition. I'm not sure if I did that. I just want to make sure we move --

09:16:48 THE COURT: You did. You did that on Friday.

09:16:52 All right. Your next witness.

MR. LOPEZ: I think we're going to play one more video, and then we'll have a live witness.

THE COURT: Another one of Ms. Hudnall?

09:17:00 MR. LOPEZ: No. This is Dr. Gary Cohen. He's a professor and chair of radiology at the Lewis Katz School of Medicine at Temple University in Philadelphia, and radiologist in chief at the Temple University Hospital. He is board-certified in radiology, and fellowship trained in

09:17:21 vascular and interventional radiology. Dr. Cohen graduated from Mount Sinai School of Medicine in 1992, and started planting IVC filters in the early 1990s.

THE COURT: All right.

(Videotaped deposition played.)

09:22:18 MR. LOPEZ: That concludes that deposition, Your Honor.

Let me state for the record that the deposition, Exhibit Number 757, is trial Exhibit Number 965. I'll give you the trial -- you want me to give the trial one first.

09:22:32 Trial Exhibit 945 was deposition Exhibit Number 736, and we would offer both of those exhibits into evidence at this time.

THE COURT: And what deposition number was trial Exhibit 946?

MR. LOPEZ: No. Trial Exhibit Number 965 was

09:22:53 deposition Exhibit Number 757.

09:22:58 THE COURT: 965 is 757.

MR. LOPEZ: And trial Exhibit Number 945 was deposition Exhibit Number 736.

THE COURT: All right.

09:23:07 MR. LOPEZ: Offer them at this time, Your Honor.

MS. HELM: Your Honor, no objection subject to the Court's ruling this morning as to trial Exhibit 965.

THE COURT: All right. Those will be admitted subject to that ruling.

09:23:19 MR. LOPEZ: Thank you.

(Exhibits 945 and 965 admitted.)

THE COURT: All right. Your next witness, Mr. Lopez.

MR. O'CONNOR: Your Honor, Joe Johnson on our team will be presenting Dr. Derek Muehrcke.

09:23:34 THE COURT: Okay.

THE COURTROOM DEPUTY: Sir, if you would please come forward and raise your right hand.

DR. DEREK MUEHRCKE,

called as a witness herein, after having been first duly sworn

09:23:44 or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. JOHNSON:

Q Good morning.

A Good morning.

09:24:15 Q If you would, please tell the ladies and gentlemen of the

jury who you are.

A My name is Derek Muehrcke. I am a cardiothoracic surgeon.

Q And if you would, tell us what your practice of cardiothoracic surgery entails.

A My practice of cardiothoracic surgery involves three phases. I do cardiac surgery, I do chest thoracic surgery, and I do vascular surgery. And I do them in equal thirds.

Q And in simple terms, you're a heart surgeon?

A Yes, sir.

Q And in your day-to-day practice, you perform open heart surgeries?

A Yes, I do.

Q Do you replace and repair heart valves?

A Yes, I replace and repair heart valves.

Q Do you operate on the major blood vessels in the body?

A Yes, I do.

Q Does that include both the aorta and the vena cava?

A Yes, it does.

Q Do you hold any board certifications, Dr. Muehrcke?

A Yes, I do. I'm am board-certified in thoracic surgery.

Q Do you hold any other board certifications?

A I don't hold any now. I was board-certified in general surgery, which was a requirement to get my cardiothoracic training, but because I don't do general surgery, I don't maintain that board fellowship or ownership.

09:25:30 Q And is that the highest level of certification you can attain in your medical specialty?

A Yes, it is.

Q How long have you been board-certified?

09:25:37 A For 24 years.

Q If you would, explain to the ladies and gentlemen of the jury the formal training that you undertook in order to become a board-certified heart surgeon?

A Well, my training was a little bit different. My training

09:25:52 involved about 17 and a half years after high school. I went to a seven-year college medical school program, and then I matriculated to Harvard, where I did my general surgical training. During that period of time I had the opportunity to live over in England and be part of the National Health Care

09:26:12 Service, which I worked in for two years. And then came back and I did a year of research at the Cardiovascular Research Institute in San Francisco, California, as part of the University of California, and then came back and finished up my general surgical training. And I stayed on at Harvard to

09:26:30 do my adult cardiothoracic training and I stayed on to do a congenital heart surgery fellowship at Boston Children's, which is also part of Harvard Medical School.

Q And did you participate in a fellowship program as well?

A Yes, I did.

09:26:45 Q And where was that?

A My fellowship program was at Harvard. It was my cardiothoracic training and my congenital heart surgery training.

Q Okay. You indicated that you took time off and participated in clinical research.

A Yes, sir, I took a year off to do that.

Q Tell us a little bit more about that, please.

A I did a year of complete bench research at the Cardiovascular Research Institute at the University of California San Francisco studying myocardial blood flow and different patterns, and my specific project was trying to find the age at which neonates lose the capacity to grow new vessels to the heart. And they -- neonates with congenital anomalies have the ability to grow new blood vessels to the heart, but at some point they lose it, and we were trying to isolate the growth factors which cause that, because that would be great for some -- for an adult who had a heart attack.

Q You told us that you operate on both the aorta and the inferior vena cava.

We've learned during this trial that Bard had performed testing of its G2 filter in the bench or on the bench using sausage casing. Are there any similarities between sausage casing and the human IVC?

A No. There's no similarity between the bench testing using

09:28:02 sausage casing and a PVC tubing and the dynamic nature of an adult inferior vena cava.

Q Okay. Doctor, where are you currently in practice?

A Jacksonville, Florida.

09:28:13 Q And at what hospital or hospitals?

A The hospital I'm at is Flagler Hospital in St. Augustine. I'm a part of a group of eight cardiac surgeons and five vascular surgeons.

Q Do you hold any positions at that hospital?

09:28:26 A I'm a founding member of the group, but also I'm the chairman of the Department of Cardiothoracic & Vascular Surgery at Flagler Hospital.

Q All right. In addition to heart surgery and chest surgery and valve surgery and vascular surgery, have you implanted IVC

09:28:42 filters in your career?

A Yes, I have implanted every iteration of the Bard filters, starting with Simon Nitinol to their retrievable line of filters, including the Recovery filter, the G2 filter, which is in play in this case, the Eclipse, the Meridian, and the

09:28:59 Denali.

Q And in addition to implanting these filters, have you from time to time removed those filters?

A Yes, I have.

Q Without going into any great detail, can you tell us the

09:29:11 manner in which these filters are supposed to be implanted and

09:29:14 removed? What's the technique that you --

A Sure. Sure.

The technique for implanting these filters is a relatively simple technique. They can be inserted through the 09:29:25 groin through a venous stick, or they can be inserted through the neck through a jugular approach, depending on certain circumstances. But the vast majority of those are implanted through a femoral stick, where you stick a needle in the femoral vein, put a wire up, and using a technique called the 09:29:42 Seldinger technique, you -- over that wire, you feed a catheter and put that into the inferior vena cava.

Typically, along the guidelines of the packet that comes with the filter, called the IFU or the Information For Use, you're supposed to inject contrast and measure the size 09:30:00 of the inferior vena cava. And the importance of that is that the Bard filters are not indicated for an inferior vena cava that has a diameter of greater than 28 millimeters. So you want to measure the size of that, and then you also want to make sure that you deploy typically the filter below the renal 09:30:19 veins. And you want to try and center the device as much as possible. And after the filter has been deployed, you take out the wire and catheter, and hold pressure on the groin. So it's relatively straightforward principle.

Q All right.

09:30:34 And while in private practice, have you been provided

09:30:37 with filter brochures from Bard?
A Yes, sir.
Q Including the brochure for the G2 permanent filter?
A Yes, I have.
09:30:45 MR. JOHNSON: Greg, if you would, locate Exhibit 2045.
And, if you would, Greg, page through the entire exhibit for us.
BY MR. JOHNSON:
09:31:17 Q Doctor, do you recognize that as the G2 permanent brochure that was provided to you by Bard?
A Yes, I do.
Q And does that exhibit accurately represent the way in which this filter was marketed to you as a doctor that
09:31:29 implanted this filter when it was available?
A Yes.
MR. NORTH: Objection, Your Honor. 402. And also outside the scope of his expert report.
THE COURT: Well, overruled on 402 grounds.
09:31:40 Is this in his expert report, Mr. Johnson?
MR. JOHNSON: Specifically, no.
THE COURT: All right, the objection is sustained.
MR. JOHNSON: Okay.
BY MR. JOHNSON:
09:31:55 Q As a doctor that implanted the G2 filter, did you have

09:31:59 certain expectations as to how that filter would perform after it was implanted?

A Yes, I did.

Q And did those expectations include the fact that this

09:32:08 filter would remain in place after implantation?

MR. NORTH: Objection. Leading.

THE COURT: Sustained.

BY MR. JOHNSON:

Q Doctor, what were the expectations you had with respect to

09:32:18 the G2 filter?

A I expected the filter to do its job. The filters are placed into the inferior vena cava to catch clots and not move.

Q And why would it be important that the filter not move?

09:32:32 A Well, the migration of the filter can be very deadly. If it were to migrate in a cephalad direction, towards the heart, it can be caught in the heart and cause death.

And the G2 filter, which we learned with time has a propensity to migrate caudally -- "caudally" means towards

09:32:53 your tail when -- and we do have a remnant of a tail, but it means downward. And the G2 filter has a propensity to migrate in a caudal fashion, which sets off a cascade or domino effect of several modalities of failure. And we would -- that's what we would see with the G2 filter.

09:33:17 Q All right. And, if you would, can you tell us about that

09:33:21 domino effect. What is the domino effect that you're referring to?

A Well, in my experience, using these filters, the G2 filter had a problem with caudal migration. It would move inferiorly
09:33:36 towards your tail. Pardon the word, but basically a caudal migration represents instability in the filter and twisting and part of the filter forming -- tilting down and falling back a small amount. And that has several consequences. When you have a caudal migration you get tilt. Tilt is very
09:33:55 important because once the filter is tilted, it doesn't function as effectively as a normal filter does in stopping clots.

The second consequence of the caudal migration after the tilting is that you have penetration of the arms and legs.
09:34:11 And the G2 filter, like all the Bard removable filters, have six arms and six legs, and they're kind of a double layer of clot-trapping ability. And once you have the caudal migration, the tilting, then you have penetration or perforation, whichever term you prefer, and the arms and legs
09:34:34 start to poke through the vena cava, and they can interact, unfortunately, with local organs, such as the aorta or the vertebral vein or the psoas muscle.

The other consequence of the tilting of the filter and the perforation is that we'll oftentimes have a fixation
09:34:56 of the filter in two spots. So the tip will migrate and touch

09:35:01 the sidewall of the vena cava, and then on the other part you have a metal fragment which is through the wall of the vena cava. And because of the dynamic nature of the vena cava moving, what you have is basically a very thin paperclip which 09:35:18 you are twisting and moving, and you're going to fracture that because of fatigue over time. And that can lead to other consequences such as fracture of fragments or embolization where those fragments will blast off and go to some other part of the body.

09:35:35 Q Okay. Let me back up a second. You had mentioned the aorta. Maybe the ladies and gentlemen are familiar with that, but what is that vessel and what is the importance of that vessel?

A The arteries take the blood away from the heart and the 09:35:47 veins bring it back to the heart. The major artery of the heart is called the aorta. And the aorta leaves the heart, goes up the coronary arteries first, goes up to the right arm, goes up the right arm vessels, goes up head vessels, comes around, goes up the left leg vessels, comes down to the 09:36:04 diaphragm, goes off the kidney arteries, and then the aorta continues down to your legs.

The venous system, the major vessels in the venous system are the vena cava. There's a superior vena cava, which is above the heart, and an inferior vena cava below the heart. 09:36:19 And these venous structures are very dynamic, very compliant,

09:36:23 and they take all the blood from the body which is being returned and bring it back to the heart.

The important thing to remember is that if you develop a clot in your leg, that clot can break off and go 09:36:37 through the venous system up to the heart, through the heart, and into the pulmonary arteries, and that can cause death if the clot is big enough.

The lungs have the capacity to absorb a large amount of small clots, but one large clot can cause what we call a 09:36:53 saddle embolus, and it gets stuck in the bottleneck of the pulmonary artery and can cause cardiac death pretty quickly.

So the aorta is the major arterial blood supply, and the vena cava is the venous return.

Q And just so we have some understanding, how are those two 09:37:11 vessels oriented --

A They're right next to each other.

Q All right. And what would be the significance of a filter perforating through the vena cava and then penetrating into the aorta?

09:37:22 A Well, it can cause mischief. I mean, it can cause bleeding, infection, it can dissect the aorta, which would be a catastrophic event. It's not something which you want to do.

Q Are the intestines also in close proximity to the vena 09:37:38 cava?

09:37:39 A The intestines are in close proximity. If you have that sequence of events, that cascade or domino effect of the caudal migration, the tilt, the perforation, the perforation can go into local structures, such as the intestines, and can
09:37:57 perforate the intestines and cause bleeding, infection, obstruction.

Q And you also mentioned the possibility that when this domino effect occurs, that the filter can actually fracture?

A Yes, sir.

09:38:12 Q What's the significance of that when fracture occurs?

A That is a very dangerous situation. The fragments can break off and they can stay locally, or they can kind of blast off and go to the heart or to the lungs.

Q All right. As part of your work as an expert in this
09:38:31 case, have you had an opportunity to review internal Bard documents?

A Yes, I have.

Q And can you give us some understanding as to the number of documents you've reviewed.

09:38:43 A A large number of documents. More documents than I had a chance to probably review in totality, but enough documents to come to an opinion about what I was reading and what I was seeing.

Q Before your involvement as an expert in this case, had
09:38:57 those documents ever been made available to you in your

09:39:00 private practice?
A No. Those documents are not available to doctors.
Q Had that information in those documents ever been made available to you in your private practice?
09:39:10 A Never.
Q And do you have an understanding that outside of this courtroom, Doctor, you are prohibited from discussing those documents?
A Yes. I've signed a protective order which does not allow
09:39:21 me to talk about what I've learned --
MR. NORTH: Objection, Your Honor --
THE WITNESS: -- from reading the --
THE COURT: Hold on just a minute.
What's the objection?
09:39:28 MR. NORTH: 402.
THE COURT: Sustained.
BY MR. JOHNSON:
Q Doctor, have you also had an opportunity to review the deposition testimony given by current and former Bard
09:39:37 employees?
A Yes, I have.
Q Have you reviewed the deposition testimony given by Rob Carr?
A Yes, I have.
09:39:43 Q Have you reviewed the deposition testimony given by

09:39:45 Dr. David Ciavarella?
A Yes.
Q Have you reviewed the deposition testimony given by Natalie Wong?
09:39:53 A Yes.
Q Have you reviewed the deposition testimony given by Janet Hudnall?
A Yes.
Q In addition to the materials that we just discussed, have
09:40:03 you had an opportunity to review Mrs. Booker's or Ms. Booker's medical records?
A Yes, I have.
Q Do those records include the implantation records? That is, the records when her G2 filter was implanted?
09:40:16 A Yes.
Q And at the time her filter was implanted, was it indicated for permanent placement only?
A I believe her filter was appropriately placed and appropriately indicated at the time it was implanted.
09:40:27 Q And was it indicated only for permanent placement at that time?
A Yes. Her device, the G2, at the time it was implanted, was only a permanent device, not a recoverable device.
Q Have you also had an opportunity also to review the
09:40:41 procedure note, the records relating to the partial removal of

this filter by Dr. Kang?

A Yes, I have.

Q Have you had an opportunity to review the open heart surgery records regarding the surgery performed by Dr. Harvey?

A Yes, I have.

Q Have you also had an opportunity to review imaging studies to include CT scans?

A Yes, I have.

Q Does that include the CT scans performed in 2011 and 2014?

A Yes, I've reviewed those CT scans.

Q Have you reviewed EKGs?

A I have reviewed EKGs.

Q Have you reviewed echocardiograms?

A Yes, sir.

Q Have you reviewed nuclear profusion testing?

A Yes.

Q And let's take those one by one.

Explain to us what an EKG is. What is the purpose of it?

A So an EKG is a very commonly performed procedure. It is a representation of the electronic -- electric activity stimulating the heart to beat. And the EKG can give information, such as a heart rate, it can show signs of ischemia or delayed conduction, it can show you evidence of left ventricular hypertrophy. An EKG is a superficial

09:41:53 noninvasive testing to look at the activity of the heart.
Q Does it provide information as to whether a patient has or has not had a heart attack?
A Yes, it does.
09:42:04 Q What is an echocardiogram?
A An echocardiogram or ultrasound is a study performed, a surface study, or it can be a transesophageal ultrasound done through the esophagus to look at the heart function. And it uses ultrasound waves to identify the function of the heart
09:42:23 and the heart valves, and structures in the heart can be seen.
Q Does it provide you, as a doctor, with information as to whether the heart is functioning in a normal fashion or an abnormal fashion?
A Yes, it does.
09:42:37 Q What is a nuclear profusion scan?
A A nuclear profusion scan is a scan which is performed under periods of stress and under rest, and it gives you an opportunity to see if there's any evidence of ischemia to the heart or a lack of blood supply to the heart. You can also
09:42:58 determine cardiac function with a nuclear scan.
Q Have you reviewed these -- not all of them, but some of these studies that were performed both before Ms. Booker's open heart surgery and that were performed after her open heart surgery?
09:43:16 A Yes, I have.

09:43:17 Q And why was that important that you review those studies?
A Well, I think it's important to see what her function was like before the heart surgery, and whether she had any damage due to her heart afterwards. The echocardiogram in Ms. Booker
09:43:31 is very important because it demonstrated her moderately severe to severe tricuspid valve regurgitation prior to her open heart surgery. And then postoperatively, it's important to see what sort of result Dr. Harvey got from his repair. But also it's important to follow the function of the heart.
09:43:54 Q Was there any evidence based on EKG, based on the echocardiograms or nuclear profusion testing, as to whether Ms. Booker had any abnormal heart function before her filter was placed?
A I did not see any evidence of abnormal heart function
09:44:11 before or after her surgery.
Q Was there any evidence she had sustained a heart attack before her filter was placed?
A No. I did not see any evidence of a heart attack, nor evidence of ischemia on the stress testing.
09:44:24 Q And just so we can orient ourself to the timeline, was the mitral regurgitation that you referred to after Dr. Kang attempted to remove the filter?
A The tricuspid, you're referring to?
Q Yes, sir.
09:44:37 A There was tricuspid regurgitation after Dr. Kang tried to

09:44:41 remove the filter fragment in her right ventricle.
Q Was there any evidence of tricuspid regurgitation that existed before Dr. Kang attempted to remove that filter?
A Not that I'm aware of.
09:44:52 Q And just so, again, we understand one another, what technique did Dr. Kang use in his attempt to remove the filter?
A Dr. Kang used a couple techniques. He initially tried to retrieve the filter with a cone from above. He stuck the
09:45:11 internal jugular vein, putting a wire down and then putting rather large venous catheter over that, or tunnel. And inside that there's a special device which is made by Bard to help capture the filter. And he had difficulty capturing the filter with the cone retrieval device, so changed over to a
09:45:33 wire snare, and that snare was able to grasp the tip of the filter cone and retrieve it into the -- bring it into the larger catheter so that the arms and legs fold in and you can pull it out.
Q All right.
09:45:50 MR. JOHNSON: Greg, can you pull up Exhibit 4376, please, and show it to Dr. Muehrcke.
BY MR. JOHNSON:
Q Dr. Muehrcke, can you tell us generally what that exhibit is?
09:46:04 A This is a exhibit of the modes of failure of Ms. Booker's

09:46:10 G2 filter.
Q Does that accurately reflect the failure modes that Ms. Booker experienced with her G2 filter?
A Yes, it does.
09:46:19 Q Would that exhibit assist you in testifying and describing for this jury the various failure modes experienced by Ms. Booker?
A Sure.
MR. JOHNSON: Your Honor, I would move to publish 09:46:28 this exhibit as a demonstrative exhibit.
THE COURT: Any objection?
MR. NORTH: No objection as a demonstrative, Your Honor.
THE COURT: All right. You may.
09:46:39 BY MR. JOHNSON:
Q All right. Doctor, let's start with the first failure mode. It says caudal migration. I think you told us what that is?
A Yes. Caudal migration is the -- represents instability of 09:46:50 the filter with a portion of the filter moving backwards and tilting.
Q All right. And you just went to bullet point 2.
There was filter tilt?
A Yes. Tilt is important because a tilted filter is not as 09:47:04 effective in catching clots.

09:47:06 Q And in Ms. Booker's situation, did her filter, did the struts of the filter actually penetrate through the vena cava?
A Yes. The -- eight of 12 struts perforated through the vena cava.
09:47:19 Q And so there were eight different areas of her vena cava that were perforated by this filter?
A Yes.
Q The next bullet point references penetration of nearby structures. Tell us about that.
09:47:32 A Well, three of the tines, or metal pieces off of the filter, per- -- one of them perforated the aorta, one of them perforated a muscle around her vertebral body called the psoas muscle. And one of them penetrated into a vein along the spine. The lumbar spine area.
09:47:58 Q In her case there were penetrations into three separate vital structures?
A Yes, sir.
Q I know you mentioned this a little while ago, but there was penetration into the aorta?
09:48:09 A Yes.
Q And is that a significant penetration?
A Yes. That's a significant penetration.
Q With respect to the psoas muscle, what is that?
A The psoas muscle is the muscle along the sides of the
09:48:21 vertebral body.

09:48:23 Q What is the significance of the fact that there was penetration into --

A Well, it can cause pain. It can also cause damage to the muscle. I mean, it could lead to bleeding and infection.

09:48:33 Q With respect to the penetration into the lumbar spine and the lumbar vein, what is the significance of that?

A Well, the significance of that is that it can cause bleeding if it were to -- it can cause bleeding or it can cause thrombosis of the vein.

09:48:48 Q The next bullet point references filter fractures, three pieces.

Explain what you mean by that.

A Well, we'll go along with the kind of cascade or domino effect of the modes of failure. The final one is fracture of

09:49:06 the arms and legs of the vena cava filter, which really represents the deterioration of the filter.

And when there's fracture, that's dangerous because the pieces can stay locally or they can move, or they can embolize. But, also, when you deteriorate the structural

09:49:27 integrity of the vena cava filter, presumably its ability to catch clots diminishes commensurately to the number of fragments fractured.

Q All right.

A And the filter fracture, the fractured fragments, one of

09:49:45 them was able to be removed from the vena cava by Dr. Kang.

09:49:49 One was not able to be removed from the vena cava. And one fracture had moved to the heart, and Dr. Kang eventually tried to remove that filter fracture from the heart, and inadvertently damaged the tricuspid valve, which Dr. Harvey had to go in and repair.

09:50:08 Q Let me go back to some of your earlier testimony. We talked about Dr. Kang and his attempt to remove the filter, and I might have asked a bad question.

Was he able to remove the main body of the filter?

09:50:23 A Dr. Kang was able to remove the main G2 filter, yes.

Q And what technique did he use to remove that filter?

A He used a snare from above to get the filter out.

Q Was that technique, in essence, the same technique that was used to implant this filter?

09:50:44 A No. No. The filter was placed from below.

Q Okay. In terms of it being a percutaneous technique.

A Yes, it was a percutaneous technique, not an open technique. Yes.

Q Okay. Is there a fragment that remains in Ms. Booker's

09:50:59 vena cava today?

A Yes, sir.

Q All right. And then there was a third fragment, metal fragment, that apparently migrated up to the heart?

A Yes.

09:51:08 Q What part of the heart did it settle in?

09:51:11 A The filter fragment which embolized to the heart went up the vena cava, past the renal veins, went into the right atrium, went through the tricuspid valve, and got caught into the trabeculations or muscle fibers of the right ventricle.

09:51:34 Q And, if you would, tell us what the function of the right ventricle is as it relates to heart function.

A So there are two venticles; there's a right ventricle and a left ventricle. The right ventricle is involved with pumping blood to the lungs to oxygenate the blood and to

09:51:52 remove waste products, such as carbon dioxide, and also it's involved with heat exchange. Pulmonary artery pressures are lower, they're 26 over 12. So the right ventricle tends to be thinner-walled, less well developed, and not able to take strain on, to take strain. If you were to have a problem with

09:52:13 a pulmonary embolus, it can't fight that.

The left ven- -- the blood goes through the lungs, the oxygenated blood comes through the lungs, comes back into the left atrium. At the left atrium it goes into the left ventricle. From the left ventricle, the blood is pumped to

09:52:30 the body with a much higher pressure, like 120 over 80, so the left ventricle is seven to eight times thicker than the right ventricle and -- to allow blood to be ejected through the body.

Q All right.

09:52:41 MR. JOHNSON: Greg, can you locate Exhibit 2248,

09:52:42 which is in evidence.

BY MR. JOHNSON:

Q Doctor, with respect to Exhibit 2248, that is a caudal migration test result performed by Natalie Wong.

09:53:47 Is that one of the documents you reviewed?

A I don't have it up on my screen.

Yes, it is. It is one of the caudal migration tests, is one of the documents which I reviewed.

Q All right. And is that one of the documents you relied

09:54:02 upon in formulating your opinions in this case?

A Yes, sir.

MR. JOHNSON: And, Greg, if you could go to page 20 of that exhibit.

And if you would blow up that box.

09:54:21 BY MR. JOHNSON:

Q Doctor, the test result obtained by Ms. Wong indicates that there was --

MR. NORTH: Your Honor, I'm going to object. I think this was specifically addressed in your *Daubert* order.

09:54:36 THE COURT: I don't know what you're referring to, Counsel.

MR. NORTH: Unacceptable.

THE COURT: I still don't. Do we need to talk about that?

09:54:43 MR. NORTH: Yeah.

09:54:43 THE COURT: We're going to have a brief sidebar, ladies and gentlemen. Feel free to stand up if you'd like.

(Bench conference as follows:)

THE COURT: All right. Would you explain.

09:55:13 MR. NORTH: Yes. Beginning on page 7. This is the document by Natalie Wong where she says unacceptable rate of caudal migration. He had given an opinion in his report that it was unacceptable. You discussed this and said that he could not parrot this report, essentially, and should not be

09:55:33 permitted to opine on Bard filter failure rates.

THE COURT: Let me interrupt you for just a minute. Where are you going with this, Mr. Johnson?

MR. JOHNSON: Judge, it is in evidence, and I was just going to ask him whether or not that information was ever

09:55:44 provided to him in his practice, is it important, is this the kind of information he would want to know about and would expect.

THE COURT: Do you object to him being asked if he would want to know this in his practice and would expect to

09:55:57 receive it?

MR. NORTH: I do because -- it is the term "unacceptable," that phrase, that he doesn't have the personal knowledge about, he doesn't have the background about. And he's just parroting what she said without the context --

09:56:11 THE COURT: Well, but he's not going to --

09:56:11 As I understand it, you're not going to have him state an opinion as to whether it was unacceptable --

MR. JOHNSON: If true, yes, sir.

09:56:20 THE COURT: So it seems to me the evidence is whether he would have expected to receive disclosure from Bard about a risk that Bard characterized as unacceptable.

Do you have a basis for objecting to that?

MR. NORTH: I still think the term "unacceptable" here is a term of art, as we've heard already in Ms. Wong's

09:56:37 deposition, and he doesn't have the context for that. So I think add 402 and 403.

THE COURT: All right. But I take it you no longer rely on my order because I did, I think, say that he could opine about what a reasonable physician would expect to

09:56:53 receive.

MR. NORTH: Right. Right.

THE COURT: All right.

MR. NORTH: It was unclear where that was going.

THE COURT: I understand.

09:56:58 My ruling on this is that you can ask him the questions about whether he would have expected to receive it. The fact the word "unacceptable" is used is in the Bard document and it's in evidence, you shouldn't ask him anything to suggest that he agrees with it because I've ruled on that.

09:57:14 MR. JOHNSON: I won't do that.

09:57:15 THE COURT: Okay.

(Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

MR. JOHNSON: May I proceed, Judge?

09:57:42 THE COURT: You may.

BY MR. JOHNSON:

Q Dr. Muehrcke, with respect to this determination by Natalie Wong that there was an unacceptable risk per the FMEA relative to the G2 filter, if true, was that information ever

09:58:02 provided to you as a doctor in your private practice?

A No, it was not.

Q Is that the kind of information that you, as a user of this filter, would have expected and would have wanted to have known about?

09:58:19 A Well, I think that any manufacturer probably knows the most about their product more than the doctors do. And the way that we get our information is from the reps from the company, from the marketing materials, and from the packet which comes with the device called the Information for Use.

09:58:35 And if information like this is not relayed in any of those three fashions, then I couldn't tell a patient about that. And, as a physician, I would like to put the safest device in my patients. For several reasons. Because it is the right thing to do, because they'll be treated better, and

09:58:58 so I don't have to worry about problems. And without

09:59:00 information like this, it is impossible for me to get a true informed consent and to tell the patients that -- what is -- why I think this filter is a better filter than another one, because I really want to use the safest filter.

09:59:15 Q All right. You made mention of the domino effect associated with the G2 filter.

A Yes.

Q Is this finding by Ms. Wong at all significant to you as it relates to that domino effect?

09:59:30 A Well, it just shows clarity. One of the things which, for me, when I had an opportunity under the protective order to look at the Bard documents and to see the true nature of how these devices performed, I stopped using them. I stopped using all Bard filters. Ethically and morally, I couldn't do

09:59:57 that. But I'm not allowed to tell my patients about the problems.

So, yeah, this is the first step in that cascade. The caudal migration initiates the entire sequence of events which leads to these filters self-destructing.

10:00:13 MR. JOHNSON: And, if you would, Greg, just briefly pull up 4376 one more time.

BY MR. JOHNSON:

Q Are the failure modes that are described in this exhibit the cascade of events that you just mentioned?

10:00:38 A Yes.

10:00:44 MR. JOHNSON: Greg, Exhibit 994, please, for the witness only.

And if you would page through that exhibit.

MR. WOODY: Page 2?

10:01:09 MR. JOHNSON: Yes, sir.

And the next page.

Page 1, please.

BY MR. JOHNSON:

Q Dr. Muehrcke, are you familiar with Exhibit 994?

10:01:25 A Yes, I am.

Q Do you recognize that as the G2 IFU?

A Yes, I do.

Q And for the permanent filter that Ms. Booker received?

A Yes.

10:01:37 MR. JOHNSON: Your Honor, we would move that exhibit into evidence.

MR. NORTH: No objection, Your Honor.

THE COURT: 994 is admitted.

(Exhibit 994admitted.)

10:01:46 BY MR. JOHNSON:

Q Doctor, we're not going to go through this document, but with respect to the warnings about this filter that are contained in that document, do they adequately warn about the failure modes experienced by Ms. Booker?

10:02:01 A No, they don't.

10:02:03 MR. NORTH: I object. Outside the scope of his report, I believe.

THE COURT: Is this in the report, Mr. Johnson?

MR. JOHNSON: Specifically, it's not.

10:02:13 THE COURT: All right. The objection is sustained.

MR. JOHNSON: Greg, Exhibit 1585, which is in evidence.

BY MR. JOHNSON:

Q Doctor, you're familiar with the G2 and G2X fracture

10:02:36 analysis?

A Yes, sir.

Q Is that a document you reviewed as part of your work as an expert in this case?

A Yes, it is.

10:02:43 Q Is that a document that you relied upon?

A Yes.

MR. JOHNSON: And, Greg, if would you, locate page 3 of that exhibit.

THE COURT: Traci, is this in evidence?

10:02:54 THE COURTROOM DEPUTY: No.

THE COURT: This is not in evidence, Mr. Johnson. My authority tells me that's true. 1585.

THE COURTROOM DEPUTY: It's not in.

MR. JOHNSON: I apologize. I thought this was in

10:03:06 evidence.

10:03:06 THE COURT: All right.

MR. JOHNSON: All right. Take that down, please.

BY MR. JOHNSON:

Q Doctor, what is a differential diagnosis?

10:03:18 A A differential diagnosis is a process that physicians go through in an effort to try to think of all possible causes of a disease state, to determine what is the most likely cause of that problem or disease state.

Q And with respect to the document that was generated by

10:03:41 Natalie Wong, Bard's quality assurance engineer, where she determined that there was an unacceptable risk with respect to the G2 filter, do you have an understanding or do you know that that document was prepared approximately 15 months before --

10:04:00 A Yes.

Q -- Ms. Booker received her filter?

A Yes. That document was generated well before she had her filter placed, her G2 filter placed.

Q And, Doctor, based on your practice as a heart surgeon, as

10:04:13 a chest surgeon, as a doctor that works on the vessels in the body, having reviewed the Bard documents, having reviewed Ms. Booker's records, medical records and her CT scan, do you have an opinion as to whether her G2 filter tilted in the vena cava, whether the struts of the filter perforated through the

10:04:37 vena cava in multiple areas, whether the struts of the filter

10:04:41 penetrated nearby vital structures, and whether the struts of the filter fractured into three pieces as a result of this filter's inadequate migration resistance?

A Yes, I do. I believe --

10:04:55 Q What is that?

A I believe that the filter had all those modalities of failure because of it's migration resistance.

Q And did you perform a differential diagnosis in arriving at that opinion?

10:05:07 A Yes, I did.

Q Is there any other reasonable cause for these multiple failure events, in your opinion, other than inadequate migration resistance?

A I could find no other reasonable causes for the caudal

10:05:19 migration and the failure modes, other than migration resistance problems.

Q Doctor, if a G2 filter is properly placed in an appropriately sized vena cava, do you have an opinion as to whether doctors would reasonably expect the G2 filter to stay

10:05:39 in place and not caudally migrate?

A Yes --

MR. NORTH: Objection. Your Honor, I believe this is cumulative. Dr. Streiff has already talked at length about physician expectations.

10:05:50 THE COURT: Overruled.

10:05:51 BY MR. JOHNSON:
Q You can answer, Doctor.
A As a reasonable physician, I would expect the Bard G2 filter to stay put and catch clots, as it's marketed.
10:06:02 Q And, Doctor, if Ms. Booker's G2 filter was properly placed, would you have expected it to stay in place and not caudally migrate?
A Correct, I would.
Q And if Ms. Booker's G2 filter was properly placed, would
10:06:16 you have an expectation that it would remain centered in the vena cava and not tilt?
A Yes.
Q What is that opinion?
A That I would expect it to stay centered and not move.
10:06:27 Q And if Ms. Booker's G2 filter was properly placed, would you have an opinion as to whether it would secure itself to the vena cava and not perforate through that vessel?
A Yes. It should stay put and not perforate.
Q And would you have an expectation, Doctor, that the G2
10:06:47 filter implanted in Ms. Booker, if properly implanted, would not in turn penetrate into adjacent vital structures?
A That is correct. I would expect it not to perforate into adjacent organs if it stayed centered in the vena cava.
Q And if Ms. Booker's G2 filter was properly placed, would
10:07:09 you have an expectation that the filter would remain intact

and would not fracture?

A Yes.

Q Was Ms. Booker's filter properly implanted?

A Yes, it appeared to be properly implanted.

Q Was the size of her vena cava appropriate for the G2 filter?

A Yes. Her size of her inferior vena cava was less than 28 millimeters.

Q In your practice as a heart surgeon, as a chest surgeon, as a vascular surgeon, do you perform a risk-benefit analysis on a daily basis?

A On every patient I operate on.

Q And, if you would, tell us what that analysis is conceptually.

A Well, on every patient I operate on, it's important to get informed consent and tell a patient, morally and ethically, what my assessment of the situation is, what specifically I think the risks are.

For instance, with open heart surgery we, get into pretty detailed statistics: What is the likelihood of you dying? What's the likelihood of you having a stroke? What is the likelihood of us having to reoperate on you for bleeding? What's the likelihood of you having an infection? What's the likelihood of your long-term recovery, and how long will it take? People have very specific answers.

10:08:25 I operate on people who are very well and people who are very ill. And the risk-benefit ratio is basically a scale of the benefit versus the risk. So some people, most people who I operate on, have a relatively low risk with left main 10:08:43 disease and good ventricular function, but they have a huge benefit, so the risk-benefit ratio is in favor of operating.

If patients are more sick and the operation's more difficult, their long-term benefit is not so good, then the scale becomes even. And it's okay to operate on people like 10:08:59 that as long as everybody is informed of that. This is a situation where grandma is not going to live as long as she'd like, but she does have her full faculties. So I think the risk of surgery is reasonable, I will do it. But your expectations also have to be commensurate with her risk and 10:09:16 the reward.

So the risk-benefit ratio has to be done for every patient to decide whether you're going to operate or not.

Q And when you have that discussion with your patients, how detailed are you?

10:09:28 A I'm very detailed.

Q How detailed?

A Well, I'm down to specifically statistical numbers as far as what the rates of this or that are. And the patient and family members have an opportunity to ask me questions. 10:09:42 Doctor, what do you think about this? What do you think about

10:09:46 that? Will grandma be able to do this again? Will grandma be able to do that again?

So it is fairly detailed and it is interactive.

Q And do you undertake that same risk-benefit analysis and 10:09:56 have that same discussion with your patients when you implant a medical device?

A Yes.

Q And when you find yourself implanting a medical device, such as a Bard G2 filter, how important is information from 10:10:10 the device manufacturer to you?

A Very important. It's the only information I get, except for the literature.

Q Doctor, let's use Natalie Wong again, where she determined 15 months before Ms. Booker received her G2 filter and 10:10:31 determined that it had an unacceptable safety risk.

Based upon that information and based upon your experience as a doctor implanting these filters, do you have an opinion as to whether the risks associated with the G2 filter outweighed any alleged benefits in Ms. Booker's case?

10:10:53 A Yeah. I mean, there's a couple aspects to that question which are very important. And the benefit of an inferior vena cava filter is only realized if the filter catches a clot, which is a rare event, and Ms. Booker has no documented cases of a pulmonary embolus or deep vein thrombosis while her 10:11:18 filter was in place.

10:11:19 But within eight months of her filter being in position, it had tilted and caudally migrated and had absolutely no benefit for catching clots, but was all total risk after that.

10:11:31 I think in the totality, the risk-benefit ratio is such that the risk of the filter at the time of implantation outweighed any benefit from the filter. And we know now from the literature, because these things have been on the market for a while, that the longer the filter is in place, the more

10:11:51 complications you see. So although you may see several people who are asymptomatic, those patients have not been followed. No one's followed those filters to see what they're up to.

It took Ms. Booker seven years before she came back to the emergency room with back pain and chest pain before

10:12:08 someone looked and found that her filter had completely disintegrated.

So the risk-benefit ratio is very important. And in her, I think that the risk of the filter outweighed any benefit from the get-go.

10:12:21 Q I want to go back to something you said in that answer, just to make sure that everybody understands your testimony.

You indicated that within eight months of the placement of the filter in Ms. Booker that it had caudally migrated and tilted?

10:12:36 A Yes.

10:12:37 Q Is that the unacceptable risk, the very unacceptable risk that Ms. Wong determined existed in this filter?

A That's exactly what she described.

MR. JOHNSON: Greg, pull up demonstrative Exhibit 4376 again.

10:12:57 BY MR. JOHNSON:

Q Doctor, with respect to all of these failure modes that Ms. Booker experienced with her filter, the caudal migration, the tilt, eight struts perforating through the vena cava, three struts penetrating into vital structures, three pieces of this filter fracturing, one of which migrated to the right ventricle of the heart, do you have an opinion as to whether the filter at that point in time afforded Ms. Booker any benefit?

10:13:31 A No. This is all risk, no benefit.

MR. JOHNSON: And, Greg, if you would, please locate Exhibit 2344, and just show that to the witness.

BY MR. JOHNSON:

Q Doctor, can you tell us whether or not that is an image from the CT scan that was performed on Ms. Booker on June 26, 2014?

A Yes. This is a CT scan image of Ms. Booker's chest.

Q Is that one of many images?

A Yes. It's one of many.

10:14:19 Q And that's an isolated image that shows what?

10:14:22 A It's an isolated image which shows a filter fragment in her heart.
Q And would that assist you, Doctor, in explaining the failure mode Ms. Booker experienced with respect to the
10:14:36 fracture of the filter that then migrated to the right ventricle of her heart?
A I'm sorry, could you repeat the question again.
Q Sure. Would that image assist you in explaining to the jury the failure mode of the filter fracture with the metal
10:14:51 fragment migrating to the right ventricle of the heart?
A Yes. It's very illustrative.
THE COURT: Judge, we would ask that we be permitted to publish that image.
MR. NORTH: No objection, Your Honor.
10:15:04 THE COURT: All right. So this is a demonstrative?
MR. JOHNSON: I move it into evidence, Your Honor.
THE COURT: Any objection?
MR. NORTH: No objection, Your Honor.
THE COURT: All right. We will admit 2344, and you
10:15:11 may publish it.
(Exhibit 2344admitted.)
BY MR. JOHNSON:
Q Dr. Muehrcke, I think your screen has a telestrator feature to it, so feel free to use that in responding to my
10:15:22 questions.

10:15:23 A Please bear with me, I've never done this before.
Q Before we talk about what you've circled, can you explain what a CT scan is, how -- orient us as to what that is.
A So a CT scan is a -- basically X-rays taken at multiple
10:15:43 different projections. And the images are acquired by cutting you this way and looking up from your feet. So the left is on the right-hand side, the right is on the left-hand side. So look at this as if you're looking up from the feet.
And it gives you cross-sectional images of the body,
10:15:59 and this is an image which shows the right and left hemidiaphragms in each thorax, it shows you the cardiac structures in the center, the heart is in the middle. And there is a metallic object lengthwise in the right ventricle along the septum.
10:16:18 Q Okay. You used a couple of big terms. You said the hemidiaphragm. What is that and where is it on this image?
A So the diaphragms are here and here. And the heart sits on the diaphragm. So we're just coming into the -- we're just coming out of the abdomen, into the chest, and we're having --
10:16:38 these are cuts of kind of the undersurface of the heart, showing both the -- here is the right ventricle, and here's the left ventricle over here.
Q All right. And do we see the aorta on that image?
A The aorta is right here.
10:16:56 Q And you have circled an object on that image.

10:17:03 A Yes. The metallic object?
Q Yes. What is that metallic object?
A So that is a 3.1 centimeter long fragment from the G2 filter that Ms. Booker had placed in 2007.
10:17:15 Q So that is a metal fragment that broke loose from Ms. Booker's G2 filter?
A Yes.
Q And moved up to her heart?
A Yes.
10:17:36 Q Did Ms. Booker ultimately undergo open heart surgery to remove that fragment?
A Yes, she did.
Q And, if you would, describe for us the surgical procedures prior to the open heart surgery that necessitated the ultimate
10:17:52 surgery performed by Dr. Harvey.
A So describe the procedures performed by Dr. Kang?
Q Yes, sir.
A Dr. Kang attempted to percutaneously retrieve this filter fracture in the heart and during the process inadvertently
10:18:11 damaged the tricuspid valve and the chordae tendineae, which are the structures which attach the tricuspid valve to the muscle of the right ventricle. And that necessitated the open procedure by Dr. Harvey to extract the foreign body and to repair the tricuspid valve.
10:18:32 Q All right.

10:18:34 With respect to the minimally invasive percutaneous procedure performed by Dr. Kang, do you have an opinion as to whether that was appropriate under these circumstances?

A Yes. It is appropriate.

10:18:48 Q Why was it appropriate, as opposed to going straight to open heart surgery?

A I think that Dr. Kang and Dr. Harvey and Dr. Harvey's other cardiothoracic partner got together and they put together a game plan, and there is -- to attempt to remove the

10:19:08 filter fragment in the heart with a percutaneous technique, which is supported in the literature, without a doubt. There's no question that that is the standard of care. And to try to remove it in a less-invasive fashion without having to go onto the heart-lung machine, cut into the chest, stop the

10:19:29 heart, and all the risk associated with the complex open heart surgical procedure.

Q We know that Dr. Kang was not successful in his attempt to percutaneously remove this filter fragment.

A Correct.

10:19:44 Q And you indicated that the tricuspid valve was damaged in the process?

A Yes, sir.

Q Again, this question and answer may be self-evident, but this percutaneous procedure would not have been required or

10:19:58 necessary but for the fact that this filter had fragmented?

10:20:03 A That's true.
Q And was Ms. Booker ultimately required to undergo open heart surgery?
A Yes.
10:20:13 Q Do you have an opinion as to whether it was appropriate to perform open heart surgery to remove this filter fragment?
A Yeah. I think that the attempt to remove the fragmented metallic object out of the heart was warranted because it's essentially kind of like a spike, and with the beating of the
10:20:31 heart it can work its way through. And in my experience I've seen that a few times. And if it perforates the thin wall of the right ventricle, you can certainly have bleeding around the heart, a situation where blood can accumulate outside the heart, inside of pericardial sac, causing constriction of the
10:20:49 heart and tamponade, and you can die from that. And I certainly wouldn't want that in my heart.
Q Just to give us some context, what is the average beat per minute of the human heart?
A 60 to 80 beats per minute.
10:21:05 Q Okay. And would you have a concern about leaving this filter in the right ventricle in this environment where the heart is beating 80 times per minute?
A Very much so.
Q 24 hours per day.
10:21:23 A Yes.

10:21:23 Q Over the lifetime of, I believe, a 49-year-old female.
A Yes.
Q Okay. And why would you want this filter removed under those circumstances?
10:21:34 A Well, I would be concerned about getting called at 2 o'clock in the morning when she's arresting because this filter's perforated her ventricle, and it can be removed under a controlled situation. I think it's safer to -- the risk-benefit ratio is in favor of removing the fragment.
10:21:53 Q Would there be a real concern on your part that this filter fragment could push its way through the wall of the right ventricle?
A I would be very concerned about that.
Q And what would be the safety problems associated with that
10:22:08 for Ms. Booker?
A Well, the safety factors are if it perforates through a ventricle, it can cause bleeding from the ventricle and blood can accumulate outside of the heart but within the sac of the -- the pericardial sac, and can prevent blood from
10:22:25 entering the heart because the heart gets kind of squeezed and constricted, and that's pericardial tamponade, and that would be a life-threatening situation.
Q Would that be a medical emergency?
A It would be an absolute medical emergency.
10:22:39 Q And is it your opinion that you would rather deal with

this problem on the front end under controlled circumstances?
A Absolutely. I agree 100 percent with Dr. Harvey. Those are his sentiments also in his deposition. I agree with that. I don't know why you would wait and why you would watch that in a 49-year-old woman. I think that is irresponsible.
Q Okay.
MR. JOHNSON: Greg, if you would, please, locate Exhibit 4319 and show it to Dr. Muehrcke only.
MR. WOODY: What's the number?
MR. JOHNSON: I believe it is 4319.
BY MR. JOHNSON:
Q Doctor, this is an animation that depicts Dr. Kang's partial removal of Ms. Booker's filter?
A Yes.
Q And you've reviewed this prior to your testimony today?
A Yes, I did.
Q And does --
MR. JOHNSON: Don't play it.
BY MR. JOHNSON:
Q Does it accurately depict the partial removal procedure performed by Dr. Kang?
A Yes, it does.
Q And would it better assist you in explaining the procedures performed by Dr. Kang in removing the body of the filter, one of the fractures, and his unsuccessful attempt at

removing the metal fragment in Ms. Booker's right ventricle?

A Yes. It's a very illustrative video.

MR. JOHNSON: Your Honor, I request that we be permitted to publish this to the jury.

MR. NORTH: No objection, Your Honor.

THE COURT: You may.

This is a demonstrative; right?

MR. JOHNSON: It is, Your Honor.

THE COURT: All right. You may.

Let me just say this before you play it.

Ladies and gentlemen, you've heard us referring to demonstrative exhibits. That is an exhibit that demonstrates something that they can show in the courtroom for you to understand it, but it won't be admitted into evidence, so it won't be available to review in the jury room. It is simply to help the testimony and evidence be clearer to you.

MR. JOHNSON: Thank you, Judge.

BY MR. JOHNSON:

Q And, Dr. Muehrcke, if you would, narrate what we're seeing when this an animation starts.

A Okay. This is the interventional radiology suite where Dr. Kang, who is an interventional cardiologist, is going to attempt to remove the Bard G2 filter which is located in the inferior vena cava.

Here is the heart, the lungs. The diaphragm is where

10:25:39 the heart sits on. The diaphragm is moving up and down as the patient breathes.

And the cutaway will show you the -- the green is the inferior vena cava with the inferior vena cava filter present, 10:25:50 and the -- you can see the filter is tilted and there's tines which are outside of the filter, and it's hard to see but there are actually two local fragmented filter pieces there.

Next to the inferior vena cava is the aorta. The first attempt that Dr. Kang made was to access the 10:26:13 intrajugular vein, put down the Recovery Cone system and removal system to try to grasp the tip of the vena cava filter. He was unsuccessful, as you can see this attempt here. It's just hard to get an angle on it sometimes when it's tilted. Sometimes the tip of the G2 filter can be 10:26:31 incorporated or endothelialized into the wall of the vena cava, making it difficult to grasp it.

Q Doctor, is that cone that you just referenced a Bard device?

A Yes, sir, it is.

10:26:41 Q And he was unsuccessful in using that device?

A Yes.

Q Okay.

A The second retrieval attempt uses a loop snare, and he was able to get that loop snare around the tip of the G2 device 10:26:56 and was able to pull it back into the sheath, and then bring

10:26:58 the arms and legs in and pull it out.

And what you're going to see now are the two remaining local fragments which are retained once that device is removed.

10:27:11 Now, one of these fractures, the -- fragments, rather, the larger on the right goes into the aorta.

Q And was Dr. Kang successful in removing that fragment?

A Yes, Dr. Kang was successful in removing that fragment.

And this is the cartoon depicting that procedure.

10:27:41 Q And what dangers would have been potentially Ms. Booker exposed to with respect to this removal of this fragment?

A Well, the worst thing I've ever seen or read about is dissecting the aorta, and you can lose both your legs because of it. But bleeding, infection.

10:27:59 Q Is that a medical emergency?

A That's a medical emergency, yes, sir.

Q Was Dr. Kang successful in removing the other --

MR. JOHNSON: Stop that, please.

BY MR. JOHNSON:

10:28:05 Q -- the other fragment that is in the vena cava?

A No, he was not. That fragment is retained.

Q And where is it retained? How is it oriented in the vena cava?

A Well, it's oriented vertically. It is oriented with one

10:28:21 end sticking out, I believe, of the vena cava, abutting the

lumbar vertebral body, and there is a reaction of the vertebral body with an osteophyte, which is, I think, preventing further migration outside of the vena cava. And the other end is in the wall or inside the vena cava. It's just impossible to know by the imaging because it's not -- the resolution's not great enough to know.

MR. JOHNSON: Greg, would you start the animation, but stop it when we get to the heart.

THE WITNESS: So after --

MR. JOHNSON: Let's stop it.

BY MR. JOHNSON:

Q Doctor, if you would use your telestrator to orient us to the heart chambers and the various relevant structures seen on that animation.

A So after the removal of the inferior vena cava filter and one of the local fragments, Dr. Kang attempted to remove the fragment which is located in the right ventricle.

And this is the left ventricle. Here is the right ventricle.

We said before that the blood will come up from below, will go into the right atrium, and then go into the right ventricle, which is right here, and then the blood will be ejected into the pulmonary artery.

Q Show us where the tricuspid valve is.

A Sure.

10:29:50 The tricuspid valve is between the right atrium and the right ventricle. And this is the retained fragment which we saw, which is about 3.1 centimeters in length, which is incorporated into the trabeculae, the muscle bundles of the 10:30:15 heart which are attaching the muscle to the tricuspid valve via these chords called the chordae tendineae. And that's -- they're --

THE COURT: Excuse me, Doctor. We're going to take a morning break at this point.

10:30:27 Ladies and gentlemen, we'll resume at a quarter to the hour, and we'll excuse you at this time.

(Recess was taken from 10:30 to 10:45. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

10:46:46 You may continue, Mr. Johnson.

MR. JOHNSON: Thank you, Judge.

Greg, let's please resume the animation.

Are you able to erase the markings?

THE COURTROOM DEPUTY: Yes.

10:47:02 MR. JOHNSON: Thank you.

THE WITNESS: So once again, here is the fragment which is located in the trabeculae of the right ventricle and impaled in there.

You're going to see Dr. Kang try to extract this 10:47:25 fragment by bringing a catheter up the inferior vena cava, and

10:47:29 this would have been the pathway which this fragment would have taken to get to this location. It will go through the inferior vena cava, through the right atrium, through the tricuspid valve, and end up in the right ventricle. You can
10:47:43 see it's a hostile environment because it's moving.

Dr. Kang's trying to grasp it with a pair of forceps. And eventually does not grasp it, but does injure the tricuspid valve apparatus attempting to remove this fragment.

BY MR. JOHNSON:

10:48:00 Q And then that procedure was ultimately abandoned.

A Yes, sir.

MR. JOHNSON: Greg, if you would, pull up animation 4320.

MR. WOODY: Stop this one?

10:48:18 MR. JOHNSON: Yes, go ahead and stop this one.

BY MR. JOHNSON:

Q Doctor, with respect to animation 4320, does this accurately depict the open-heart procedure and tricuspid valve repair performed by Dr. Harvey?

10:48:40 A Yes, it does.

Q And will it assist you in explaining to the jury the complexities, if you will, of the open heart surgery performed by Dr. Harvey?

A I believe it will.

10:48:50 MR. JOHNSON: Your Honor, we would request permission

10:48:50 to publish this animation.

THE COURT: Any objection?

MR. NORTH: No objection, Your Honor.

THE COURT: You may, as a demonstrative.

10:48:59 (Video playing.)

THE WITNESS: Once again, this is the heart beating. The right and left ventricle. Left ventricle over here; right ventricle as depicted.

And there's the tricuspid valve.

10:49:21 BY MR. JOHNSON:

Q I don't think you told us, but what is the function of the tricuspid valve?

A The function of the tricuspid valve is to prevent blood from going back into the right atrium when the ventricle

10:49:32 contracts. It's basically a one-way valve to keep the fluid, the flow of blood, through the heart, out into the pulmonary arteries, which is up in here. They're all one-way valves.

Q Okay.

A If they become incompetent, then the consequences of that

10:49:49 are that the right heart will fail because you have a running motor with a leaky valve and the motor will burn out.

Q All right.

Again, orient us to --

A So this is the --

10:50:23 Q -- animation.

10:50:23 A -- operating room. Patient is sterilely prepped and draped in a supine position.

Dr. Harvey is going to try to do this through the chest wall through a minimally invasive technique. He's going 10:50:34 to make a small incision into the skin, the fat, the muscle. He's going to insert a scope to ensure that the lung is not adherent or scarred up, and he's going to try to do this through a minimally invasive incision where the lung is collapsed and falls away and gives exposure to the heart.

10:50:53 So he puts the scope in and sees there is no adhesions. He then lengthens the incision to put a chest retractor in and cuts through the muscle and spreads the ribs to allow access to the heart, and the incision will be a bit longer.

10:51:10 Specifically he's using this approach, as opposed to going through the sternum, to prevent the long-term restrictions which one would have if you did a median sternotomy incision, or incision through the middle of the chest bone, the breastbone.

10:51:26 So the right lung gets deflated. You can have a special breathing tube or just the left lung breathes and the right one is not breathing. We do this all the time when we do lung resections so we can operate on nonmoving field. But the right lung is deflated, giving better access.

10:51:42 As part of this operation, Dr. Harvey is going to go

10:51:45 out and have to run the heart-lung machine, and he has to put tubes or cannula into the arterial system and one to the venous system. And this allows the patient to go on the heart-lung machine. And the heart-lung machine takes over the
10:51:59 function of the heart and the lungs.

When you go on the heart-lung machine, Dr. Harvey's going to stop the heart and the heart-lung machine puts oxygen in the blood and moves blood around the body under force so the patient doesn't die.

10:52:14 This is exposure through the right anterior thoracotomy incision. Now he'll open up the pericardial sac that surrounds the heart and he will gain access to the heart by going through the right atrium.

The right atrium is the upper chamber above the
10:52:30 tricuspid valve.

This is a heart-lung machine here. The heart-lung machine takes the blood out of the body, puts it through the machine, which gives it oxygen, and puts it back into the body under force so you can maintain a blood pressure to the rest
10:52:44 of the body and profuse the organs while you're doing cardiopulmonary bypass.

Q Let me interrupt you for a second, Doctor. You indicated Dr. Harvey would have actually stopped the heart?

A Yes. For this operation, he had to stop the heart for an
10:52:56 hour and a half.

10:52:57 Q And is the heart receiving any blood supply during that process?

A The heart is not receiving blood supply. It's receiving cardioplegic to keep it in a rested state.

10:53:09 Q How is it that this cardioplegia keeps the heart protected during the surgery?

A Well, you cannot stop the cells from using up energy and oxygen, so you try to give them a little shot of cardioplegia every 20 or 30 minutes, and give them a potassium solution

10:53:26 which stops them beating. So the major source of oxygen consumption is the beating heart. So stopping it, cooling it, helps prevent myocardial cell death or heart cell -- prevents a heart attack, prevents the cells from dying. But the reality is, the longer the heart is cross-clamped, the more

10:53:48 heart cells will die.

Q So there are time restrictions?

A Yes. Very much so. Yeah.

Q And you indicated that Ms. Booker's heart was stopped for 90 minutes?

10:53:56 A For an hour and a half. Yes, sir.

Q And in your world of heart surgery, how would you describe that period of time? Is it mild? Moderate? How --

A Well, it's moderate to getting long. I've done it longer. But usually my cross-cut times are hopefully under an hour.

10:54:15 There are times when you have to stop a heart for two hours,

two and a half hours. When do you that, you may need help to separate the patient from the heart-lung machine, such as pressor agents or a balloon pump or a ventricular assist device.

Q In a patient like Ms. Booker whose heart has stopped for 90 minutes, what concerns do you have as a heart surgeon?

A Well, any time your blood leaves your body and goes through an artificial system it can clot and you initiate a protective mechanism of the body called an inflammatory response.

It's kind of like a big wooden splinter was put down the middle of your back. Your body reacts to it, and all the cells react to it. And there are a number of manifestations of it to the body, but in general, it's amazing how well it's tolerated, but you can have -- you can die from it. There's 1 percent risk of death just going on the heart-lung machine.

But, you know, it's -- she did fairly well with it, but she did require blood transfusions as a consequence of going on the heart-lung machine.

Q In light of the fact the heart is actually arrested or stopped, is this heart-lung machine designed to supply blood to the rest of the body?

A Yes. Rest of the body is being profused with oxygenated blood and the temperature's controlled.

Q All right.

10:55:36 MR. JOHNSON: And go ahead and continue the animation.

THE WITNESS: Now snares are put around the superior, inferior vena cava so blood would not be in the operative 10:55:55 field.

BY MR. JOHNSON:

Q Is that the cross-clamping you referred to?

A No. No. The cross-clamp is going to come on next on the aorta so it will stop the blood -- it will limit the blood 10:56:08 coming back to the heart, and a special tubing will be put in there to give the cardioplegia solution which will stop the heart.

So the cross-clamp's being applied across the aorta so the heart is isolated now and a cardioplegia needle is 10:56:23 inserted, and the blue solution represents the high potassium solution which stops the heart diastolely, and therefore you can operate on a nonmoving target.

Q And I'm going to ask some questions, but continue the narration.

10:56:37 Where is the incision ultimately made by Dr. Harvey?

A Right into the right atrium. The retractors show the exposed tricuspid valve. The posterior leaflet has a red line on it, which represents a tear, which was caused during the attempt to remove the filter fragment.

10:56:56 Working through that tricuspid valve, Dr. Harvey's

10:57:01 going to make an effort to extract the foreign body.

You can see severed chordae tendineae, which are ruptured, and you can see the filter fragment both on the CTA images here and also in the cartoon.

10:57:19 And Dr. Harvey had a hard time getting this fragment out. It took him quite a while searching for it.

And this is the picture we showed a little bit earlier showing the filter fragment on the CT scan.

Q Now, it appears this fragment is in the bottom of the

10:57:34 right ventricle.

A Yes, sir.

Q And how does that make this surgery more difficult or easier?

A Well, it was woven into the chordae trabeculae, which are

10:57:46 the muscles. So it was very hard for Dr. Harvey, according to his operative report, to see it. He actually had to incise the muscle, which causes the damage to the heart. And there is some evidence on EKGs of widening of his QRS complex, consistent with a partial right bundle branch block which is

10:58:05 affecting the conduction system to the right ventricle.

Q What is the significance of that as it relates to Ms. Booker?

A Well, if it gets bad enough, it can require a pacemaker. If it progresses. But basically it represents there's

10:58:17 scarring because of the -- and that myocardium had to be cut

10:58:20 and they made incisions close to the conduction system, it looks like, to the heart.

Eventually Dr. Harvey does grasp the fragment with the right-angle clamp he's using, and then extracts the 10:58:35 fragment.

Q And is he actually trying to grasp this fragment by passing this clamp through the tricuspid valve?

A Yes. Yes. That's the preferred approach, as opposed to going through the ventricle, because the ventricle will bleed 10:58:51 a lot and would be more difficult to repair.

Next Dr. Harvey turns attention to the tricuspid valve and does a complex repair, which is not usually done, but he's able to suture the posterior leaflet to the anterior leaflet to retain a repair, and used a ring, a very small 10:59:09 ring, a 26 ring. Normally I use a 32 in the tricuspid valve.

But the -- he obtained a fairly good result with trivial tricuspid regurgitation. But my concern is that the severed chordae still remains, so the structural integrity of the tricuspid valve is not as pristine as in its natural 10:59:29 state, and gives me concerns for the long-term durability of this repair as to if Ms. Booker goes on to develop tricuspid regurgitation. If she develops tricuspid regurgitation in the future, my concern is that she may be need to be re-operated on and have to have the tricuspid valve replaced with a 10:59:53 prosthesis.

10:59:55 Q You indicated that the incision was made into and through the right atrium to gain access to this fragment.

A Yes.

Q How is that technique different than the traditional heart

11:00:08 bypass surgery that we've all heard about?

A Well, this is a much more complex procedure. The most common operation I do for heart surgery is coronary artery bypass grafting. Coronary artery disease is the most common cause of death in America. And my operation involves

11:00:25 operating on the surface of the heart. This operation involves actually opening up the heart and incising muscle in the right ventricular cavity. And the consequences are more significant of cutting out muscle and injury to the conduction system, arrhythmias, and the future scarring. Possibility of

11:00:49 getting air. You have to de-air the heart, you know, carefully.

Q With respect to Ms. Booker, what are the real concerns by virtue of the fact that Dr. Harvey had to actually cut through the right atrium through the heart muscle?

11:01:05 A Arrhythmias. But my concerns are the complex nature of the repair. This is a complex repair but it's not a conventional repair. You're not going to see a picture of this type of repair in any textbook of cardiac surgery. Dr. Harvey did a very good job of doing this on the fly.

11:01:24 My concern is that the structural integrity of the

11:01:28 tricuspid valve has been compromised because of the transected chordal attachments to the valve. I'm concerned about the long-term durability of that valve. Concerned about scarring from where he incised the fragment in the right ventricle to
11:01:44 remove it.

But even more importantly I'm concerned about that retained fragment in the inferior vena cava because if that fragment were to blast off again, the whole process could be repeated again.

11:01:55 Q With respect to the tricuspid valve, you indicated you have concerns about the durability of the repair.

A Yes, sir.

Q Dr. Harvey did not perform mitral -- I'm sorry, a tricuspid valve replacement; is that right?

11:02:06 A He did not. He repaired the valve.

Q And I believe Ms. Booker's currently 49 years of age. Given her relatively young age, do you have an opinion as to whether she is likely to require a future heart surgery to either repair or replace the tricuspid valve?

11:02:23 A Well, there's a couple issues there. One is her -- I think it's likely she may require a valve replacement in the future. But more concerning is if you look at the literature on people who have had tricuspid valve repair or replacements, their ten-year survival is 66 percent. So her long-term
11:02:44 survival has been diminished because of the need for tricuspid

11:02:48 valve surgery.

Q With respect to her tricuspid valve repair, do you have an opinion as to whether she requires medical monitoring?

A Oh, absolutely. She needs monitoring of the retained 11:03:02 filter fracture in the inferior vena cava which was not able to be removed. She needs to have CT scans yearly to monitor that fragment, that rogue fragment which could not be removed. She needs to have CT scans -- I'm sorry. She needs to have echocardiograms and EKGs of her heart done every year and 11:03:24 followup with a cardiologist.

Q With respect to the incision through the ribs, I believe you indicated that is called a thoracotomy?

A Yes, sir.

Q Do you have an opinion as to whether she is going to 11:03:39 experience pain for the rest of her life related --

A I think she's had pain. Not only from the inflammation from around the sac of the heart called pericarditis, and I think she's also had a pain from the incision in her chest called post thoracotomy pain syndrome. It has to do with the 11:03:58 retractor pressing up against the nerve bundle underneath the rib and compressing it and causing damage. I think she's had both those, from what I saw in the record.

Q Is she at risk to developing arrhythmias?

A Yes, she's at risk of developing arrhythmias in the 11:04:14 future.

11:04:15 Q Is that a life-threatening situation?
A Well, it can be. I think that her risk -- she hasn't had a problem now. I would defer to an electrophysiologist about that. My -- I would -- I think with the scarring, which we
11:04:27 talked about before, can lead to a right bundle branch block. And a right bundle branch block is essentially a block in the conduction system, the electrical activity, to the right heart.

The right and left heart conduction systems work
11:04:44 together to synchronize the contraction of the right and left heart, and that can cause problems in the future which might require a pacemaker.
Q You mentioned the conduction system. That's the electrical system of the heart?
11:04:58 A Yes. When we're born as neonates -- when we're in fetus, I guess, if you go back any further, the myocardial cells are one of the rare tissues in the body that has the ability to dedifferentiate to muscle or to nervous tissue. And part of the heart muscles dedifferentiate to nerve tissues which make
11:05:18 up the conduction system of the heart which allows electrical impulses to synchronize the contraction of the heart.
Q Doctor, what is constrictive heart failure?
A Well, constrictive cardiomyopathy is where an inflammation occurs of the sac, the pericardial sac around the heart, and
11:05:38 the inflammation gets severe enough to restrict the ability of

11:05:42 the heart to fill.

Q All right. And what is constrictive pericarditis?

A That is pretty much the same thing. It's the heart failure is the component where you cannot get enough blood

11:05:55 into the heart to pump it through the body and then the process is constricted pericarditis.

Q And is right heart failure the same thing?

A Right heart failure would be part of it. Constrictive pericarditis would probably attack both the right and left

11:06:08 heart.

Q With respect to Ms. Booker being at risk for arrhythmias; right heart failure, constrictive pericarditis, and her reduced life expectancy, are these, in your opinion, all the result of this filter having fragmented and then migrated to

11:06:28 the right ventricle of the heart?

A Yes.

MR. JOHNSON: Greg, let's go to Exhibit 2052.

And, Judge, my mistake in the earlier reference to 1585. There appears to be a duplication in the exhibit list.

11:06:46 And I believe 2052 is in evidence.

THE COURTROOM DEPUTY: Yes, 2052 is admitted.

THE COURT: It is.

MR. JOHNSON: Greg, let's quickly move to Page 18 of this exhibit.

11:07:08 I request permission to publish this to the jury.

11:07:11 THE COURT: You may.

BY MR. JOHNSON:

Q Doctor, do you see where there is a chart on Page 18 of this exhibit -- I'd like you to assume this is a Bard exhibit, 11:07:23 this is not a plaintiffs-created exhibit -- where Bard is comparing the G2 filter to the Recovery filter?

A Yes.

Q And just so we understand the iterations, the G2 was the newer filter, it replaced the Recovery filter.

11:07:40 A Correct.

Q And do you see where the first item that compares the G2 filter to the RNF filter, the Recovery filter, references a type A fracture and a type B fracture?

A Yes, sir.

11:07:53 Q If you would, explain to the jury what a type A fracture is and what a type B fracture is.

A So this is a complex matrix of a comparison between the G2 and the RNF or the retrievable Nitinol filter, which is also called a Recovery filter.

11:08:09 The first line is type A and type B fractures. Type A fractures are more significant. Felt to be more deadly fractures, the type of fractures where the fragment would either go to the heart, the lungs, or outside of the vascular system, or they would penetrate organs, I believe. I can't 11:08:30 remember -- there's one other criteria I can't remember off

11:08:32 the top of my head.

But they're -- basically the type A fractures are more -- felt to be more dangerous or life-threatening than the type B filters. And you can see that the second generation 11:08:44 retrievable filter, the so-called G2 filter, has a higher number of type A fractures compared to the retrievable Nitinol filter or the Recovery filter, as it's also called.

Q Did Ms. Booker suffer or experience a tape A fracture?

A Yes, she did. She had a fragment which went to the heart, 11:09:05 so -- which would be a type A fracture.

Q And does this comparative table indicate that the G2 is worse than the Recovery filter as relates to type A fractures?

A Yes, sir.

MR. NORTH: Objection, Your Honor. 602. No 11:09:22 foundation.

THE COURT: Overruled based on just the reading of the table.

MR. JOHNSON: Greg, let's go down to the caudal migration comparison.

11:09:36 BY MR. JOHNSON:

Q Again, just to reorient us, you told us earlier caudal migration is where the filter drops down?

A Um-hmm. Yes, sir.

Q And that is -- that causes this domino effect that you 11:09:49 described?

11:09:49 A Yes.

For some reason, with the new generation of retrievable filters which Bard put out, the second generation of the so-called G2, they had a caudal migration problem with
11:10:01 it. And I'm not so sure anybody really understands what it was.

But the incidence of the caudal migration, as you can see in the comments section, G2 more caudal migration than the Recovery filter.

11:10:15 And that's a problem. It's a problem because this filter was -- the Recovery filter was changed. There were structural changes made to the Recovery filter to make the G2 filter, and that was never tested. There were never long-term studies done that were tested in patients. And these were the
11:10:36 results, and these results were never given to the doctors to know about.

Q Does this comparative table indicate to you this downward migration for the G2 filter is worse compared to the Recovery filter?

11:10:47 A Absolutely. 14 percent versus 3.

Q The next item is cephalad migration. That is an upward migration?

A Yes. That's towards the head. They're the same. They're no different.

11:10:56 Q The same.

11:10:56 Let's go to tilt, please. And with respect to tilt, what does this comparative table indicate?

A The new generation, the G2 filter which Ms. Booker had, has a higher incidence of tilt than the Recovery filter did.

11:11:14 Q And the next item is perforation. What does this comparative table indicate?

A Once again, the G2 filter had a much higher rate of perforation than the earlier model of the Recovery filter did.

Q Based on having reviewed this comparative table, how would

11:11:29 you describe the safety profile of a G2 filter compared to the Recovery filter?

A Well, when you take it in the totality and the information which we as physicians were given from Bard to determine the marketing, we were told that the new G2 filter brought

11:11:45 strength and stability --

MR. NORTH: Objection. Outside the scope. Talking about marketing.

THE COURT: Is this in the report?

MR. JOHNSON: No, Your Honor.

11:11:53 THE COURT: Objection is sustained.

BY MR. JOHNSON:

Q If you would, just tell us what this indicates regarding the safety profile of the G2 --

A I think the G2 is less safe than the Recovery filter.

11:12:03 MR. JOHNSON: I pass the witness, Your Honor.

THE COURT: All right.

Cross-examination?

MR. NORTH: Thank you, Your Honor.

C R O S S - E X A M I N A T I O N

BY MR. NORTH:

Q Good morning, Dr. Muehrcke.

A Good morning. Good afternoon.

Q You and I have met on one previous occasion when I took your deposition; correct?

A Correct.

MR. NORTH: Mr. Russell, if we could turn to the same exhibit we just had up, I believe it was Exhibit 2052. Plaintiffs.

BY MR. NORTH:

Q And this was the document that you were just asked a number of questions about, true, Dr. Muehrcke?

A True.

Q If we could turn to the second page of that same document.

And this document is reflecting complaints received by Bard for the G2 and the G2X through November 30th of 2008; correct?

A You have to point me to where -- yes, okay, I see it. November 30th. Yes, sir.

Q And if you look in that table, it demonstrates that as of that date there had been 100,000-plus of these G2 filters

sold; correct?

A Yes.

Q Do you know what an MDR is?

A I'm not sure I -- I'm --

Q Well, look down to like the fourth or fifth row, where it says total number of MDRs.

A Okay.

Q Do you know what that means?

A I don't know, no. You have to fill me in.

Q I'd like for you to assume for a moment that an MDR is a report -- a complaint of some adverse event regarding the filter. Correct?

A Correct.

Q Okay. If this is reporting in all of these charts and all of these percentages you were just talking about are concerning 56 adverse events out of 100,000 G2s sold, that's a very small number of adverse events, isn't it?

A This is for all G2s?

Q And G2Xs.

A The problem is that the commercial complaint rate is a number which is 0.06, seems rather small, but the numerator is 56 but the denominator is units sold, it's not units implanted. So this is going to give you a number which is kind of artificially low.

Q Well, let's assume -- I mean, these filters cost some

11:14:50 money, don't they?

A They do cost money.

Q Okay. Let's assume that that 100,000 number is double from what the number of filters implanted. If only 50,000 of

11:15:03 those filters had been implanted, 56 adverse events would still be a very low number; correct?

A Well, it's a relatively low number, but I'd be concerned of the fact that the G2 filter's much worse than the Recovery filter.

11:15:19 Q And you're willing to make that decision based on 56 adverse events?

A This is the exact type of information I think doctors need to have when they're implanting this device.

Q You're willing to draw a conclusion about the performance

11:15:33 of a device based on 56 out of possibly 100,000 adverse events?

A When I put these devices in patients, I try give them the safest device I possibly can, and having more information, from my perspective, is better. It may seem like it's a small

11:15:50 number, but I want to put the safest device in my patients. I think I really need to know that information before I can start implanting them.

Q When you were comparing those numbers, the number of type A fractures with type B fractures, the number of cephalad

11:16:07 versus caudal migrations, did you realize at the time that you

were looking at a grand -- percentages concerning a grand total of 56 adverse events?

A I wasn't sure that that's what it represents. It's just a table which shows a comparison between the Recovery filter and the G2 showing that the G2 filter is not as good as the predicate Recovery device.

Q Again, according to that document, it shows that, in your opinion, based on 56 events out of 100,000 sold.

A Well, the problem -- the problem is that Bard underreports its results. There's a 2015 letter from the FDA --

MR. NORTH: Your Honor, I object.

THE COURT: Please respond to the question, if you would, Doctor.

THE WITNESS: I'm sorry, can you repeat the question.

THE COURT: Reask the question.

BY MR. NORTH:

Q Your opinion was based on 56 complaints received at that point out of 100,000 sold; correct?

A If the final table is made for 56 patients, that's true.

Q Let me ask you this: You're charging the plaintiffs a fee to be here today; correct?

A Yes, I am.

Q As I understand it, you're charging them $650 an hour?

A Yes, sir.

Q And you also charged them for the time spent reviewing the

Bard documents; correct?

A That's correct.

Q And you spent -- charged them for the time spent Ms. Booker -- reviewing Ms. Booker's medical records; correct?

A I did.

Q And that amount of time in reviewing those records totaled up to charges of approximately $22,000, didn't it?

A No, that's not correct. That's not correct. The total bill for the five --

Q For the Booker case.

A For the Booker case was $22,000? I don't -- I don't -- I don't know if I can confirm that.

Q Well, you charged $4,500 for your deposition in this case; correct?

A Yes.

Q And you're charging -- tell the jury how much you're charging to spend for each day in Phoenix.

A $5,000 for trial. For the entire situation.

Q So do you charge $5,000 per day or just 5,000 for the entire trip out here?

A For the entire trip out here.

Q And when did you come out here?

A I came out here yesterday.

Q So you had charged the plaintiffs at least 10- or $15,000 so far for your work on this case; correct?

11:18:26 A Yes. But when I'm not in my office seeing patients or operating, I have expenses. I'm a businessman. I have to pay for the rent, I have to pay for the lights, I have to pay for salaries, and I lose earnings. So I think this is a very
11:18:43 important topic that needs to be discussed, and I'm happy to be here but I unfortunately can't do it for free, I have bills to pay.

Q I believe you told us earlier in response to some of Mr. Johnson's questions that, in your opinion, this filter was
11:19:00 appropriately placed in Ms. Booker; correct?

A Yes.

Q And you believe that Ms. Filter -- Ms. Booker needed a filter at the time it was placed; correct?

A I think at the time it was within the standard of care,
11:19:12 yes.

Q And that's because she had had a recent history of pulmonary embolism; correct?

A And could not be on a coagulate, she had bleeding, was anticipating surgery, yes.

11:19:23 Q And in your practice, would you implant a filter in a patient in her situation?

A I would -- I'm not sure I would do that now.

Q Back in 2007 would you have done that?

A In 2007, yes, I would have.

11:19:41 Q Now, I believe you also told us in response to one of

11:19:43 Mr. Johnson's questions that you saw no evidence of any damage to her heart prior to Dr. Kang's procedure; correct?

A Yes.

Q And after the heart surgery by Dr. Harvey, you saw no

11:19:56 damage to her heart.

A The only damage I saw was the change in her EKG from before -- I think I saw the EKGs from 9:00 in the morning the day of her attempted extraction by Dr. Kang. I saw an EKG after the extraction, and her QRS complex was small or narrow.

11:20:15 And then after the surgical procedure, her QRS had widened into a partial bundle branch block. So that's the only injury I saw. But her ventricular function was still maintained.

Q So the heart performance was essentially normal after Dr. Harvey's surgery?

11:20:31 A Yes.

Q And I believe you also told us that there was no evidence of any damage to her tricuspid valve in her heart until Dr. Kang performed that procedure to try to remove the strut; correct?

11:20:44 A Yes.

Q And for that reason, it was not the strut passing through the valve that damaged the valve, it was what Dr. Kang did; correct?

A Well, I -- I think it's most likely what Dr. Kang did.

11:20:57 But at my deposition I said it might be the filter fragment

11:21:00 going through it. I think it's more clear to me now that it's probably the attempted recovery of that filter fragment. Especially when it was associated with the life-threatening arrhythmias during the attempt by Dr. Kang to remove it.

11:21:16 Q You mentioned earlier you saw no evidence in the tests of a heart attack; correct?

A Correct.

Q Were you shown the medical records from the early 2000s when she was -- Ms. Booker was hospitalized on two separate

11:21:28 occasions and had cardiac events?

A Yeah. And I also saw the cardiologist evaluation of that with the stress testing showing that she has no evidence of heart attack from the cardiologist, and I saw her stress tests showing she didn't have any coronary ischemia.

11:21:45 Q And when were those tests performed?

A They were performed in the -- I think it was -- I can't remember. 2012 or something. She had -- he mentioned two episodes of anaphylactic reaction to antibiotics, and I think that might have been construed as heart attacks.

11:22:04 Q Doctor, my question did not concern 2012. I'm talking about 2000, the year 2000, and the year 2001. Did you see medical records of hospitalizations during that time period?

A I understand she was hospitalized. I understand that she thought she had had heart attacks. What I'm saying is I don't

11:22:22 think she had heart attacks. I think those were anaphylactic

11:22:25 reactions to antibiotics.
Q But you have not seen the records from those hospitalizations; correct?
A I have seen -- I have not seen the specific admissions,
11:22:34 but I've seen the reference to them in her medical records and I've seen the cardiologist who specifically addressed that issue.
Q You've seen the references in her medical records from later years --
11:22:47 A Yes, sir.
Q -- but you have not seen the actual medical records in 2000 and 2001 when she was hospitalized; correct?
A Correct. She's not suffered significant damage at all. I don't think she's had a heart attack. Of any significance.
11:23:06 Q I believe you told us in response to one of Mr. Johnson's questions that you quit using Bard filters after you saw the documents that the plaintiff's attorneys provided you; correct?
A That's correct.
11:23:20 Q So up until the time that you were furnished these documents, you still implanted Bard filters in your patients?
A Denalis, yes.
Q Are you aware -- you are aware of the fact, as you told us in your deposition, that Bard produced hundreds of thousands
11:23:37 of documents in this litigation; correct?

11:23:39 A Yes.
Q And you were only furnished approximately 20 or 25 of those hundreds of thousands of documents; correct?
A Correct.
11:23:51 Q And you had the opportunity to review additional documents, but you did not take that opportunity; correct?
A Correct.
Q And the 20 to 25 documents from Bard that you reviewed --
A I reviewed more than 25 documents from Bard.
11:24:13 Q I thought you just told us you received 20 to 25 from Bard -- from the plaintiff's attorneys.
A No. I received multiple documents from Bard. More than 25. But I've received enough documents to make an opinion about what doctors should have been told and what they were
11:24:30 not.
Q You don't remember telling us in your deposition that you had reviewed 20 to 25 documents from Bard?
A Well, not 25 pages. 25 separate reports -- I mean some of these analyses are 18 pages long.
11:24:48 Q I understand that. I'm talking about documents, not pages.
A Okay.
Q But in totality --
A Just don't want it to be misconstrued I looked at 25
11:24:57 pieces of paper and made an opinion.

Q I'm talking about complete documents, whether they're one page or 500 pages.
A Okay.
Q Am I correct that, as you told us in your deposition, you've only reviewed 20 to 25 Bard documents?
A Correct.
Q And that's out of the hundreds of thousands that were produced?
A Yes.
Q And even though you had the opportunity to review additional ones, you did not.
A I didn't see it necessary.
Q And so based upon -- your decision to quit using Bard filters was based solely on the review of 20 to 25 documents provided to you by the plaintiff's attorneys; correct?
A Sure. Would you like me to explain?
Q I'm just asking you is that correct?
A Would you like me to explain?
Q Mr. Johnson may ask you that. Is that correct?
A Okay. That's correct.
Q You are aware that in the five years before Ms. Booker had the filter implanted, she had suffered pulmonary embolisms on two separate occasions; correct?
A Yes.
Q And you are aware that in the seven years after the filter

was implanted she was never diagnosed with a pulmonary embolism; correct?

A That's correct.

Q And to this day, you do still place filters on occasion in your patients; correct?

A On occasion. Much less than I used to.

Q And you believe IVC filters can benefit certain patients; correct?

A Well, that's interesting. I think that that's changed quite a bit because I don't think there's any paper that's ever shown an IVC filter saved a life.

Q But you still implant them sometimes, don't you?

A In very select cases.

Q And you also, when you implant filters, know that filters carry risks; correct?

A Filters can carry risks, yes.

Q In fact, as you told us before, all inferior vena cava filters can migrate?

A They can migrate, yes.

Q And all inferior vena cava filters, as you told us, can fracture?

A That's true.

Q And all inferior vena cava filters can penetrate; correct?

A They can penetrate.

Q And all inferior vena cava filters can caudally migrate?

11:27:14 A They can.
Q Now, you would agree that caudal migration is a different sort of complication mode than cephalad migration; correct?
A I'm not so sure about that. I think that everybody has
11:27:24 mostly been concerned about the cephalad migration to the heart being more dangerous, but with the G2 filter I think we kind of have a new animal, and the constellation of the domino effect can lead to filter fragments which can kill people. So I don't think it's fair to say it's benign.
11:27:46 Q Well, cephalad migration to the heart, if the filter goes to the heart, that can be a catastrophic event leading to a patient death; correct?
A It can.
Q And as you told us before, you have never seen a death
11:27:59 caused by a caudal or downward migration?
A Well, I've never seen one, but I'm concerned that there have been some reports to the FDA that were not at -- not correctly identified by Bard and --
MR. NORTH: Your Honor, could we approach the bench?
11:28:16 I object to his statement and ask if we could approach the bench.
THE COURT: Yeah, you can approach.
If you want to stand up for a minute, ladies and gentlemen, please do.
11:28:23 (Bench conference as follows:

11:28:37 MR. NORTH: Your Honor, he's going into the FDA warning letter for the second time. He's talking about -- I'm asking him if he's aware of any, and he starts launching into caudal -- he's aware that things hadn't been appropriately 11:28:50 characterized to the FDA. Not only is it not responsive, but it is opening up the door to the warning letter, it's in violation of the order on the motion in limine, and I'm concerned that they've not instructed this witness as they should have on that issue.

11:29:04 MR. JOHNSON: Judge, he has been instructed, but I think Mr. North has asked -- I think he's opened the door, in all honesty. He asked a very broad question to which this witness is giving an answer, and I think the answer is a reflection of the broadly worded question or phrased question 11:29:19 by Mr. North.

THE COURT: Well, I -- I think this witness is venturing well beyond the questions in his answers. He's trying to make points he feels are important, and he has mentioned the FDA letter once. I don't know if he was going 11:29:31 to this time, but he's now getting into Bard reports.

It seems to me the way to deal with that, Mr. North, is for you to ask him if he can answer a question yes or no. If he can't, then tell you he can't. And I'll reinforce you on that. So you can control your cross-examination.

11:29:50 MR. NORTH: Okay.

11:29:50 THE COURT: If he's still on -- he probably won't be after the lunch break. I was going to say you could re-admonish him, but I don't think we ought to take a break to do that.

11:29:59 MR. NORTH: I agree.

THE COURT: But, yeah, you can control the witness through yes or no questions, and if he can't say yes or no, to tell you.

MR. NORTH: Okay.

11:30:06 THE COURT: And I'll back you up. I'm not going to let him wander if you object.

MR. NORTH: Thank you.

(Bench conference concludes.)

BY MR. NORTH:

11:30:24 Q Let me ask you this, Dr. Muehrcke, as I was saying beforehand: Can you tell me, yes or no, whether you have seen a death caused by a caudal migration?

A Myself?

Q Yes.

11:30:33 A I don't know that I've seen one.

Q You read medical journals and medical articles as a part of your practice; correct?

A Yes, I do.

Q Have you ever seen a medical article concerning a death

11:30:46 caused by a caudal migration?

11:30:50 A Well, that's kind of hard to answer.
Q Doctor, can you answer that yes or no?
A I don't think I can answer that yes or no. Would you like to know why?
11:30:56 THE COURT: Doctor, if he asks you to answer yes or no and you can, please do so. If you can't, you can tell him --
THE WITNESS: I can't answer that yes or no --
THE COURT: Hold on just a minute.
11:31:05 If you can't, tell him, and he can reask another question.
THE WITNESS: I can't answer that.
BY MR. NORTH:
Q As you sit here today, do you specifically recall having
11:31:14 seen a medical article concerning a death caused by caudal migration?
A I cannot answer that.
Q So you cannot recall one way or the other whether you have seen a medical article where the authors attributed a death of
11:31:32 a patient to a caudal migration?
A I cannot answer that because I don't know that the authors are looking for caudal migration. That's not -- they'll just report deaths.
Q My question was, have you seen an article where the
11:31:47 authors associated in the article, whether they missed it or

11:31:52 saw it, but whether they associated a caudal migration with the death of a patient? Have you personally seen one?

A I don't know of any articles that have looked at deaths due to caudal migrations.

11:32:04 Q So what you're telling us is you can't recall having seen one?

A That's exactly what I'm telling you.

Q Thank you.

And in your practice, you have never had a Bard 11:32:14 filter fracture that necessitated open surgery; correct?

A I have not.

Q And yet in your practice, you have had to perform open surgeries on a patient who had another manufacturer's filter, a Greenfield --

11:32:30 A Greenfield.

Q -- filter fracture; correct?

A Yes, sir.

Q Now, you testified earlier that you believed, in your opinion, that this filter had tilted within eight months and 11:32:48 that therefore it provided no benefit to Ms. Booker thereafter; correct?

A Yes.

Q Now, as a part of these 20 to 25 of the hundreds of thousands of documents, Bard documents, provided to you and 11:33:01 selected by the plaintiff's attorneys, did they provide you

11:33:05 with a copy of the test reports assessing the efficiency, clot-trapping efficiency, of tilted filters?
A Well, I asked for those documents --
Q Can you answer my question yes or no?
11:33:19 A I can't answer your question. I asked for the documents. It's a misrepresentation -- I mean, I -- I reviewed these Kessler reports and the other experts and asked for those documents from my attorneys.
Q The question wasn't whether you asked for the documents.
11:33:38 My question was, out of the 20 to 25 documents that the plaintiff's attorneys selected for you and gave to you, were one of those -- did one of those documents include Bard's testing on the clot-trapping efficiencies of tilted filters? Yes or no?
11:33:56 A No.
Q And so when you are reaching -- expressing an opinion to this jury about how efficient -- or whether a tilted filter can capture clots, you're giving that opinion without seeing the Bard tests on that issue; correct?
11:34:13 A Oh, I've seen Bard's tests on that issue. I did not -- my -- it was not given to me by my lawyers until I asked for it. I've seen the -- we talked about this in my deposition. I've seen the Bard tests which looked at the efficiency of the Bard filter when it is tilted as consistent with the
11:34:35 literature that when the filters tilt, they don't function as

11:34:40 well.

And there's also a Bard-sponsored implanters conference in Chicago at the Hilton Hotel where that was discussed by Bard. There's documents from that, too, which 11:34:57 talk about Bard's concern about their tilted filters not functioning correctly.

Q I'm sorry, Doctor, I don't mean to argue with you, but I thought you told us just a minute ago that you had not been provided and had not seen the clot-trapping efficiency tests 11:35:13 performed by Bard, and then you now, as I understand, you're saying you did see it?

A Your question was that my lawyers handed it to me in the beginning -- as a set of documents to review. I -- I, on my own, asked them for those documents to confirm that I had 11:35:30 concerns about the ability of the filter to function when it's tilted more than 15 degrees.

Q So did you or did you not review the Bard test report on clotting efficiency?

A I did. I did.

11:35:41 Q And you still hold the opinion that Ms. Booker's filter did not capture clots once it was tilted?

A I believe that the efficiency of the filter declines after it's tilted more than 15 degrees.

Q Okay. If it's your opinion that the efficiency declines, 11:35:57 you're not able to quantify how much, are you?

11:36:01 A Well, the only quantification I give you is Rogers article that showed there's a doubling of the amount of pulmonary emboli that occur in patients who have had more than 15 degrees tilting of a conical-shaped filter, which would be 11:36:14 appropriate for Bard's filter.

Q But tilted filters still capture clots; correct?

A They may be able to. The ones that have missing arms and legs, though, I think would be even less able to catch clots.

Q As we sit here today, no one can say with certainty 11:36:31 whether Ms. Booker's filter caught a clot or did not; correct?

A That's correct.

Q And it's entirely possible that it did; we'll never know.

A Well, I think it's kind of unlikely because she hasn't had any episodes of leg swelling consistent with a deep venous 11:36:46 thrombosis, which would be the precursor to a pulmonary embolus. But you're right, nobody can tell for sure.

Q And what we do know, even though she had two pulmonary emboli before she received the filter, she never had another one after receiving the filter.

11:37:01 A I agree she's never had another one after the filter.

Q Doctor, you would agree Ms. Booker has had somewhat of a complex medical history; correct?

A Yes.

Q That she had a pulmonary embolism in 2001, and again in 11:37:21 2007?

A Yes.
Q She has a history of kidney stones.
A Yes.
Q She has a history of mitral valve prolapse.
A Yes.
Q And that involves the heart; correct?
A The mitral valve's in the heart.
Q She has had two hernia repairs over the years; correct?
A Correct.
Q And she has had an appendectomy.
A Yes.
Q And she's had cervical cancer.
A Yes.
Q And she has had the removal of several benign tumors.
A Yes.
Q Now -- and, therefore, she has necessarily had to seek medical care with some frequency over the years; correct?
A Yes.
Q Now, as a part of your work in this case, did you look at a film taken of Ms. Booker in March of 2009?
A I'd have to see it. I don't know if I have.
MR. NORTH: Could you pull up Exhibit 6825.
Okay. Let's just move along for now.
BY MR. NORTH:
Q Doctor, let me ask you this: Have you seen the film taken

several years before the actual discovery of the fractured strut that showed the filter tilted and where you could see one strut had actually fractured at that time?

A Can you give me a date? Is it 2011?

Q No. I'm talking about March 2009.

A I may have seen it. I may have seen it. I think there's a 2011 one where I saw the filter was not normal.

Q In the 2011 one you saw, was the fractured strut still adjacent to the filter?

A I believe so, yes.

Q But you're not certain whether you've seen one as early as 2009 with the fractured strut adjacent to the filter?

A If you show it to me -- I'd have to take a look at it, I just don't recall.

Q Well, let's talk about the one you do recall in 2011. No doctor at that time reported that filter strut being broken; correct?

A That's correct.

Q If that had been reported to the appropriate doctor in her care, the filter could have been moved -- removed percutaneously at that time; correct?

MR. JOHNSON: Objection, Your Honor. Outside of the scope of direct.

THE COURT: What's your response, Mr. North?

MR. NORTH: He's given a lot of opinions as to her

injury and how it developed and what the causes were and -- being the filter, and that is another cause.

THE COURT: I think the objection is sustained. I think this is outside the scope.

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q Now, the strut that remains in her heart, Dr. Muehrcke, it's been in the same position now for more than four years; correct?

A Yes.

Q And it has not moved in more than four years.

A That's my understanding.

Q And based on what you told us in your deposition, it's my understanding that you would defer to an interventional radiologist as to whether that strut in the IVC is retrievable; correct?

A Correct.

Q And you would agree there are interventional radiologists who specialize in difficult or complex retrieval of fractured struts and can do it percutaneously, either through the femoral or the jugular vein; correct?

A There are people who specialize in difficult removals.

Q Now, as you've told us, I believe, after the strut was removed from Ms. Booker's heart, you have not seen evidence sufficient to diagnose her with pericarditis; correct?

11:41:17 A Correct. Well, she's had -- she's had -- she's had pain which I think was treated as pericarditis at one point, but she's also had post-thoracotomy pain syndrome.
Q But as you told us, you have not seen evidence sufficient
11:41:35 to diagnose her with pericarditis; correct?
A I don't have an opinion on that. I don't know.
Q And you would agree that in surgical patients like Ms. Booker, as you've told us, pericarditis occurs in only 5 to 10 percent of the cases; correct?
11:41:51 A That's correct.
Q And I believe you have told us that you cannot quantify or estimate her risk of an arrhythmia or irregular heartbeat in the future; correct?
A Well, yeah, I guess I would correct that. She does have
11:42:12 an abnormal rhythm right now. She's got a partial bundle branch block, so the percentage is a hundred percent. The likelihood of requiring a pacemaker is a little more difficult for me to determine.
Q And I believe you told us it could be 1 percent,
11:42:26 2 percent, 5 percent, or something else, there's no way --
A I --
Q Let me finish, if I could, for the court reporter's sake.
There's no way to quantify that; correct?
A I think I said I'd defer to an electrophysiologist.
11:42:39 Q Right. You would defer to somebody, an

electrophysiologist, who's a physician that specializes in that sort of area.

A That's right.

Q And you consider that beyond your expertise to quantify that?

A Yes.

Q And also, as you've told us, you are unable to quantify the risk of future heart failure in Ms. Booker; correct?

A I'm very concerned about that. I cannot quantitate it, but her type of repair with uncorrected structural abnormalities of the valve at this point are concerning to me long term.

Q But as you told -- have said, you cannot quantify that risk. I understand you have concern, but you can't quantify --

A I cannot quantify it, but I think that may be a reality somewhere down the line for her.

Q And because of her various medical conditions, she is going to need to continue seeing a physician on a -- physicians on regular basis irrespective of her need to see doctors regarding her heart; correct?

A That's correct.

Q Doctor, my understanding is that when you place filters these days, you are generally placing the TrapEase filter; is that correct?

11:44:13 A No. I use the Argon Option ELITE.
Q And --
A If I use a permanent filter, I use the TrapEase.
Q And how recently did you implant a TrapEase filter?
11:44:26 A Oh, eight months, maybe a year.
Q Are you familiar with a journal called Archives of Internal Medicine?
A Yes.
Q That is actually affiliated with the American Medical
11:44:46 Association, or the AMA; correct?
A Correct.
Q Is that a reputable journal?
A Yes, it is.
Q Are the articles that appear in there peer-reviewed?
11:44:55 A They are.
MR. NORTH: Could we pull up Exhibit 7286, please.
BY MR. NORTH:
Q Doctor, have you seen this particular article, Frequent Fractures of TrapEase inferior vena cava filters, a long-term
11:45:21 follow-up assessment?
A No, I've not seen it.
MR. NORTH: Your Honor, at this time I would like to ask questions of this witness about this document and to read parts of it pursuant to 803(18), I believe, as a learned
11:45:32 treatise.

THE COURT: Any objection?

MR. JOHNSON: No, Your Honor.

THE COURT: All right. You may.

BY MR. NORTH:

Q If you could turn to the second page, please.

Under the Results section.

Doesn't this report that among the 20 patients implanted with TrapEase filters, the same filter you implanted as recently as eight months ago, ten of those had been fractured, were reported as fractured?

A That's correct.

Q And so that is a fracture rate in this TrapEase filter of 50 percent; correct?

A Correct.

Q And this goes on to report that in four years 64 percent of the TrapEase filters had been fractured; correct?

A Correct.

Q None of the Bard documents you were shown showed a 50 percent fracture rate with the G2 filter, did they?

A The -- none of the Bard information, but the literature shows a 40 percent fracture rate at five years. Two articles. But none of the Bard data that I was shown did, no.

Q None of the Bard data shown show 64 percent either, did it?

A No, they didn't.

11:47:15 Q And you continue to implant the TrapEase filter as part of your practice; correct?
A I have to because it's what the interventional radiologists use. It's not my call.
11:47:25 Q So you're saying that you're implanting the filter, not because you believe it's the appropriate filter, but because someone's telling you that's the one you've got to use?
A I think that the TrapEase is probably the best permanent filter out there. It has its problem, but it's the best one
11:47:45 that I've seen.
Q Would you consider a 50 percent fracture rate to be acceptable?
A Better than the Bard.
Q Are you familiar with the Journal of Cardiovascular and
11:48:03 Interventional Radiology?
A I don't routinely read it, but I've heard of it.
Q Do you consider it a reputable peer-reviewed journal?
A I guess. I don't really follow it.
Q Aren't you a cardiovascular surgeon?
11:48:19 A I am.
Q And you don't read this particular journal?
A The Journal of Interventional Cardio- --
Q Of Cardiovascular and Interventional Radiology.
A I do not read that journal.
11:48:37 Q Now, Doctor, you've told this jury a minute ago that the

50 percent fracture rate with the TrapEase filter, and I think I quote you, was "better than Bard."

A I -- I trust the TrapEase filter more than I trust the Bard filter, for many reasons. I mean, you can cherry pick a piper if you'd like, but I think the gestalt of my education and my experience is that I trust the TrapEase filter. The TrapEase filter does have a problem with thrombosis, but I trust that filter more than I do the Bard filter.

Q But the fact of the matter is you continued to use Bard filters until you were provided documents by the plaintiff's attorneys?

A Exactly.

MR. NORTH: That's all the questions I have. Thank you.

THE COURT: Any redirect?

MR. JOHNSON: Yes, sir.

R E D I R E C T E X A M I N A T I O N

BY MR. JOHNSON:

Q Doctor, let's first discuss the heart attack question that was posed to you.

If Ms. Booker in fact had suffered a heart attack in the year 2000, 2001, would you expect to see evidence of it in the heart tests that were performed on her as recent as 2012?

A Yes, I would. I would expect if it was significant, I would have thought she would have some abnormal heart

11:50:05 function. However, you can have an anaphylactic reaction and have a demand type of lack of blood supply to the body because you're hypotensive for a short period of time, but it's something which people usually recover from, and that sounds 11:50:22 to me more like what she had than a so-called heart attack from coronary artery disease.

Q Was there any evidence in the heart tests performed on Ms. Booker that she had, prior to this incident, ever suffered a heart attack?

11:50:36 A No. Her heart function's normal.

Q All right. And you mentioned anaphylactic shock. Did you see some records that indicated Ms. Booker had either suffered an anaphylactic shock in response to anesthesia or antibiotics or something like that?

11:50:50 A Yes. I saw a cardiologist who evaluated her for that very question, and his conclusion was that she had suffered anaphylactic shock, not myocardial infarction.

Q And in that evaluation performed by that cardiologist, was there a concern about whether she had suffered a heart attack 11:51:07 at any point in time?

A There was concern about it, yes.

Q What were the conclusions?

A He felt it was not a heart attack, it was anaphylactic shock.

11:51:15 Q Was there any objective heart test results that indicated

Ms. Booker had suffered a heart attack before she received her Bard G2 filter?

A Not that I saw.

Q With regard to the documents that you reviewed for purposes of your work in this case, we provided you with documents.

A Yes. If I have a request for one, I go to you.

Q And have we in turn given you more documents as you've requested those documents?

A Yes.

Q And so have your -- has the sum total, I guess, if you will, of the documents you've reviewed been 25 or has it been more than that?

A My recollection it's probably more than that now because I'm always calling you or Mark for more documents.

Q All right.

You were asked about Ms. Booker's extensive medical history.

A Yes.

Q She had had a hernia repair, she had -- I forgot what the other issues were. Cervical cancer. Did those medical conditions cause her filter to migrate, to tilt, to perforate, to penetrate, and to fracture?

A No.

Q Do they have anything to do with the failure modes

11:52:34 associated with Ms. Booker's filter?
A No, they don't.
Q You indicated that following Dr. Kang's partial removal of Ms. Booker's filter that there was, I believe, widening of her
11:52:52 QRS waves on EKG monitoring.
A Yes.
Q What is the significance of that and what do you attribute that to?
A Well, it occurred after she had the filter fracture
11:53:02 removed from the heart where Dr. Harvey went through the tricuspid valve with the knife, an 11 blade, and had to cut out that fragment, and I think it's probably due to injury to the conduction system of her heart --
Q All right.
11:53:14 A -- as a result of extracting the filter fragment.
Q And during this whole process, Mr. North has taken your deposition?
A Yes.
Q And he has had an opportunity to show you the other side
11:53:26 of the story, so to speak, and show you internal Bard documents?
A Yes.
Q Has he shown you any?
A No.
11:53:42 MR. JOHNSON: Greg, can you locate Exhibit 2052,

please.

And go to page 2.

And, if you would, zoom in on that.

BY MR. JOHNSON:

Q Do you see at the top it references Fracture Summary, does it not?

A Yes.

Q Does it reference caudal migration?

A No.

Q Does it reference perforation?

A No.

Q Does it reference tilt?

A No.

Q And with regard to the total number of MDRs -- you've read Dr. Ciavarella's deposition that's been given in this litigation?

A Yes, sir.

Q And you understand Dr. Ciavarella to have been the medical director for Bard?

A Yes.

Q And with regard to Dr. Ciavarella's testimony in this case, did you read, and I'll represent to you he testified by way of videotape deposition last week, that the MDR reporting rate is 1 to 5 percent of what is actually happening in the real world?

A The MAUDE data. Yes.
Q And you read that?
A Yes.
Q And do you understand that to mean that when MAUDE data is --

MR. NORTH: Object. He's leading.

THE COURT: Sustained.

BY MR. NORTH:

Q Doctor, with regard to the MDR reports, what do you understand them to reflect as it relates to the real world experience that's occurring?
A They are reported voluntarily by physicians and device makers to the FDA, and they tend to be underreported by 95 percent. Because if I come in my practice and I see a fractured filter on X-ray, I'll take the time to fill out a government form to let them know there's a fracture in a person that may be asymptomatic. And it's estimated by Dr. Ciavarella to be 95 percent underreported. And when you add to that total number of units distributed, you divide it by a higher number, you get a real low number.
Q All right. In reading Dr. Ciavarella's deposition, did you understand him to testify that despite this voluntary reporting --

MR. NORTH: Objection. Leading.

THE COURT: Sustained.

11:56:10 BY MR. JOHNSON:
Q Do you have an understanding, Doctor, as to whether Bard tracks internally its own complication rates, separate and apart from the MDR reporting?
11:56:22 A I believe there's some tracking done by Bard.
Q Okay.
MR. JOHNSON: And, if you would, Greg, go to Page 18 again.
BY MR. JOHNSON:
11:56:30 Q And with regard to page 2 and the Fracture Analysis, do you have an understanding as to whether the migration rate for caudal migration, the tilt rate, and the perforation rate, are separate and apart from the fracture rate?
A Yes. I believe so, yeah.
11:57:00 Q That is different than the fracture analysis, based on your review, of page 2?
A Correct.
MR. JOHNSON: And, Greg, if you would locate Exhibit 991 that is in evidence.
11:57:15 BY MR. JOHNSON:
Q Do you see that this is an e-mail from Dr. Ciavarella, the medical director of Bard, dated December 27, 2005, which is before Ms. Booker received her G2 filter?
A Yes.
11:57:38 Q All right.

11:57:38 MR. JOHNSON: And if you would go down, Greg.

Do you see -- let's go to the second paragraph.

The next one down.

BY MR. JOHNSON:

11:57:53 Q You were asked about the ability of the G2 filter to capture a clot when it's tilted.

A Yes.

MR. JOHNSON: Your Honor, may I publish this to the jury? It's in evidence.

11:58:12 THE COURT: Yes.

BY MR. JOHNSON:

Q And what do you understand Dr. Ciavarella, the medical director of Bard, to be saying about the clot-trapping ability of the G2 filter which it's tilted?

11:58:26 A I think he had the same concerns I have --

MR. NORTH: Objection. 602.

THE COURT: Hold on just a minute.

MR. NORTH: Objection. 602. He's asking him to interpret what Dr. Ciavarella was meaning.

11:58:36 THE COURT: Would you rephrase the question, please.

BY MR. JOHNSON:

Q Do you see where Dr. Ciavarella states, "From what you've sent me, it seems to me that the biggest, parenthetically worst case, consequence of these migrations is that they are

11:58:53 accompanied in a majority of cases by tilting. This raises

11:58:57 the concern of lack of efficacy. That is, are the filters now in place to perform clot interruption."

What does that mean to you?

A To me, he is raising the same concern I have about a tilted filter. They don't work.

11:59:11 Q You were asked about a medical article, and it was Exhibit 7286, and it involved --

THE COURT: Before we go, Mr. Johnson, we're at the noon hour. Are you close to the end?

11:59:39 MR. JOHNSON: I'm close.

THE COURT: Like within a minute?

MR. JOHNSON: Two minutes.

THE COURT: All right. Two minutes.

MR. JOHNSON: Okay.

11:59:44 BY MR. JOHNSON:

Q That involved an analysis of 20 patients who received a TrapEase filter.

A Yes.

Q And is that considered to be a level one study to assess

11:59:56 safety and efficacy of a filter?

A I -- I think -- I don't know. I didn't really read the report. I don't know much about it. Seemed like it's a cherry-picked report, though. And I don't know the time duration of it.

12:00:09 Q Do you think, having reviewed that article, is there any

12:00:13 indication that the authors of that article were provided with the same internal documents you've had the opportunity to see and review regarding the Bard filters?

A I doubt that they've gotten to see what I've seen.

12:00:26 Q Was there any indication that those authors had seen the information indicating that there was an unacceptable risk with caudal migration of the G2 filter?

A No, I don't think they've seen it.

Q Or that there was a domino efflect that -- I'm sorry, a

12:00:43 domino effect that flows from caudal migration?

A I don't think they've seen that documentation from Bard.

Q And that study looked at filter fracture; correct?

A Correct.

Q In this case you have told us about the domino effect:

12:01:00 The caudal migration, the tilt of the filter, the perforation, the penetration, and the fracture that occurs when caudal migration occurs.

A Yes.

Q What is it about the multiple failure modes that are

12:01:15 occurring with the Bard filter that is alarming to you?

A Well, it's just that, it's the frequency and the fact -- they occur more frequently than the other filters, and they all occur together. It's a constellation of a -- of a domino effect. They have more -- not only more complications, but

12:01:41 multiple complications when they fail.

12:01:44 THE COURT: That's two minutes, Mr. Johnson.
MR. JOHNSON: It's been two minutes?
THE COURT: Yeah.
MR. JOHNSON: One more question?
12:01:48 THE COURT: Last question.
BY MR. JOHNSON:
Q How are the multiple failure modes that you just discussed, in your opinion, more dangerous to a patient than a single filter fracture?
12:02:01 A Well, because --
MR. NORTH: Objection. Outside the scope of cross.
THE COURT: Was this covered in cross?
MR. NORTH: It was.
THE COURT: I don't think multiple failure rates were
12:02:12 covered.
MR. JOHNSON: Well, he was asked about the failure rate of the TrapEase, and I want to put this in perspective with the multiple failure modes.
THE COURT: The objection is sustained. I think it's
12:02:18 outside the scope.
MR. JOHNSON: That's all I have, Your Honor.
THE COURT: All right. We're going to break, ladies and gentlemen, until 1 o'clock. We will plan to see you then.
We'll excuse the jury.
12:02:27 MR. JOHNSON: One more question. Just a housekeeping

matter to Dr. Muehrcke.

THE COURT: All right. While we're all standing.

BY MR. JOHNSON:

Q Doctor, are all of the opinions you've expressed today within a reasonable degree of medical certainty?

A Yes.

MR. JOHNSON: Thank you.

THE COURT: All right. Thanks, ladies and gentlemen.

(The jury exited the courtroom at 12:02.)

THE COURT: All right, Counsel. As of the lunch hour, without any allocation of Hudnall's additional testimony, plaintiff has used 12 hours and 54 minutes, the defense four hours and seven minutes.

We'll see you at 1 o'clock.

MR. LOPEZ: Can I ask you to repeat the plaintiff's hours one more time.

THE COURT: Yes. 12 hours and 54 minutes.

MR. LOPEZ: Thank you.

(Recess taken at 12:04.)

(End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 20th day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter